EFFECT OF HIGH SAC LIGATION ON POSTOPERATIVE PAIN DURING LICHTENSTEIN'S INDIRECT INGUINAL HERNIA REPAIR

A DISSERTATION SUBMITTED TO THE TAMILNADU DR.MGR MEDICAL UNIVERSITY
In partial fulfillment of the regulations for the award of the

Degree of M.S., (GENERAL SURGERY)
BRANCH-1

DEPARTMENT OF GENERAL SURGERY

STANLEY MEDICAL COLLEGE AND HOSPITAL,

TAMILNADU DR.MGR MEDICAL UNIVERSITY, CHENNAI

APRIL 2016

DECLARATION

*I Dr.NIYAS AHAMED.N solemnly declare that this dissertation titled "**Effect of High Sac Ligation on Postoperative pain during Lichtenstein's Indirect Inguinal Hernia Repair**" is a bonafide work done by me in the Department of General Surgery, Govt. Stanley Medical College and hospital, Chennai under the supervision of* **Prof.Dr.A.K.RAJENDRAN,** Prof.Dr.P.DARWIN, Prof.Dr.V.RUKMANGATHAN, *and my head of the department* **Prof.Dr.S.VISWANATHAN**. *This dissertation is submitted to the Tamilnadu Dr. MGR Medical University, Chennai in partial fullfilment of the university regulations for the award of M.S degree(General Surgery),branch-1 examination to be held in April 2016.*

September 2015 **Dr.NIYAS AHAMED.N**

Chennai.

CERTIFICATE

This is to certify that the dissertation entitled ***"EFFECT OF HIGH SAC LIGATION ON POSTOPERATIVE PAIN DURING LICHTENSTEIN'S INDIRECT INGUINAL HERNIA REPAIR"*** *is a bonafide work done by Dr.NIYAS AHAMED.N Post Graduate(2013-2016) in the Department of General Surgery, Govt .Stanley Medical College and hospital, Chennai under my direct guidance and supervision, in partial fulfillment of the regulations of the TAMILNADU Dr.MGR MEDICAL UNIVERSITY Chennai for the award of M.S degree(General surgery) Branch-1 examination to be held in April 2016.*

Prof.Dr.A.K. RAJENDRAN M.S.,

Professor of Surgery
Dept.of General Surgery
Stanley Medical College
Chennai-1

Prof.Dr.S.VISWANATHAN M.S.,

Professor and Head of Surgery
Dept.of General Surgery
Stanley Medical College
Chennai-1

Prof.Dr.ISSAC CHRISTIAN MOSES M.D.,
The Dean
Stanley Medical College
Chennai-1

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LIST OF ABBREVATIONS

Fig. – Figure

L- Lumbar

Cm – Centimeter

VAS – Visual Analog Scale

P – Probability

r- Reliability

IP- In Patient

SL- Serial

TB- Tuberculosis

DM- Diabetes Mellitus

Temp- Temperature

PR- Pulse Rate

BP- Blood Pressure

USG- Ultrasonogram

CVS – Cardiovascular system

RS – Respiratory system

H/o – History of

POD – Postoperative Day

ABSTRACT

Background:

Tension free repair for inguinal is considered to be one of the painless operations. Mild or medium pain in the post operative period, is common, even in the mesh repair era, and is usually due to ilioinguinal nerve entrapment or mesh fixation to the periosteum of the pubic tubercle. However during indirect inguinal hernia repair, sac ligation may be the cause of pain. The aim of this study is to conduct a single-center prospective randomized trial with a view to clarify this issue on a scientific basis[1].

METHODOLOGY

- Sample size of 60 cases (30 in each group) is taken. An informed consent is obtained from them after discussion of risk versus benefit ratio.
- Patients are divided randomly in two equal groups.
- In Group A, after confirming intraoperative diagnosis of indirect inguinal hernia, hernial sac opened, its contents returned to the peritoneal cavity, ligation performed using an absorbable suture (2’0 vicryl) and the excessive sac excised.

- In group B, after confirming intraoperative diagnosis of indirect inguinal hernia, hernial sac along with the prolapsing viscera was reduced to the peritoneal cavity after opening the sac, without ligation.
- Lytle's repair(with 2'0 prolene) is done for all patients.
- Later on in both groups Lichtenstein tension-free mesh repair is performed. The main outcome measure is mean postoperative pain score using VISUAL ANALOG SCALE on 1^{st}, 7^{th} and 10^{th} post operative days.

RESULTS:

The mean postoperative pain VAS on POD-1,7 and 10 in Group A was 4.57 ± 0.5, 3.27 ± 0.74, 2.10 ± 0.61, respectively. Whereas in Group B - 3.67 ± 0.61, 2.00 ± 0.64, 1.03 ± 0.62 respectively. The p value between the two Groups on POD-1 was p=0.005, in POD-7 p=0.010, in POD-10 p=0.005.

There were no recurrences recorded among the two Groups in the follow up period of 6 months.

CONCLUSION:

Thereby it is concluded that High Sac ligation in Indirect Inguinal Hernia Lichtenstein's Repair was not only unnecessary but also causes increased postoperative pain which can be prevented without Sac ligation.

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INTRODUCTION

Inguinal hernias are the most common - comprising approximately 75 % of all anterior abdominal wall hernias[2]. Many exist in the community undiagnosed, undetected, and unreported thereby being a major economic problem. Inspite of the frequency of surgical repair, precise outcomes still continue to elude surgeons[3].

Surgical treatment of the inguinal hernias has undergone tremendous transformation in the past few decades[4]. The Lichtenstein tension-free hernioplasty began in 1984 and evolved over a period to a procedure which is now considered to be gold standard for hernia repair[5]. In this technique a wall reinforcing the fascia transversalis is created by using a prosthetic mesh.

This technique, that does not need a long learning curve, offers surgeons and their patients a short operation time on an outpatient basis, minimal complications rate, early return to work and virtually low recurrence rate even in non-expert hands[6]. Pain after inguinal hernia surgery is a common complaint in surgical wards. There are many reasons for post operative pain.

This study compares post-operative pain among patients undergoing high sac ligation versus sac reduction in elective Lichtenstein inguinal hernia repair.

AIMS & OBJECTIVES

- This study compares post-operative pain among patients undergoing high sac ligation versus sac reduction in elective Lichtenstein inguinal hernia repair.

REVIEW OF LITERATURE

HISTORY

The word “hernia” is derived from a Latin term meaning “a rupture.” The earliest reports of abdominal wall hernias date back to 1500 BC. During this early era, abdominal wall hernias were treated with trusses or bandage dressings. The first evidence of operative repair of a groin hernia dates back to the first century AD.

The original hernia repairs involved wide operative exposures through scrotal incisions requiring orchiectomy on the involved side. Centuries later, around 700 AD, principles of operative hernia repair evolved to emphasize mass ligation and en bloc excision of the hernia sac, cord, and testis distal to the external ring.

The first report of groin hernia classification based on the anatomy of the defect (ie, inguinal versus femoral) dates back to the 14th century, and the anatomical descriptions of direct and indirect types of inguinal hernia were first reported in 1559.

Bassini revolutionized the surgical repair of the groin hernia with his novel anatomical dissection and low recurrence rates. He first performed his operation in 1884, and published his initial outcomes in 1889[14]. Bassini reported 100% follow-up of patients over a 5-year period, with just five recurrences in over 250 patients. This rate of recurrence was unheard of at the time and marked a distinct turning point in the evolution of herniorraphy. Bassini's repair emphasizes both the high ligation of the hernia sac in the internal ring, as well as suture reinforcement of the posterior inguinal canal. The operation utilizes a deep and superficial closure of the inguinal canal. In the deep portion of the repair, the canal is repaired by interrupted sutures affixing the transversalis fascia medially to the inguinal ligament laterally. This requires an incision through the transversalis fascia. The superficial closure is provided by the external oblique fascia.

In addition to Bassini's contributions, the first true Cooper's ligament repair, which affixes the pectineal ligament to Poupart's ligament and thereby repairs both inguinal and femoral hernia defects, was introduced by Lotheissen in 1898. McVay further popularized the Cooper's ligament repair with the addition of a relaxing incision to reduce the increased wound tension.

The advances in groin hernia repair in the century following Bassini have shared the primary goal of reducing long-term hernia recurrence rates. To this end, efforts have been directed at developing a repair that imparts the least tension on the tissues that are brought together to repair the hernia defect. Darn repairs were first introduced in the early 20th century to reduce wound tension by using either autologous tissue or synthetic suture to bridge the gap between fascial tissues. Muscle and fascial flaps were attempted without consistent success.

In 1918, Handley introduced the first use of silk as a prosthetic darn and nylon followed several years later. However, it was found that heavy prosthetic material increased the risk of wound infection, and the silk suture ultimately lost its strength over time. The use of autologous or synthetic patches was also attempted in order to reduce wound tension and improve rates of recurrence. The first patches, beginning in the early 20th century, consisted of silver wire filigree sheets that were placed along the inguinal canal.

Over time, the sheets suffered from metal fatigue leading to hernia recurrence. Reports of the wire patches eroding into adjacent inguinal structures and even the peritoneal cavity itself caused even more concern with this technique. The modern synthetic patch, made of a plastic monofilament polymer (polyethylene), was introduced by Usher in 1958. Lichtenstein, who developed a suture less hernia repair using a plastic mesh patch placed across the inguinal floor, further popularized this technique.

In the search for a technical means to reduce recurrence , emphasis was also placed on a meticulous dissection that would avoid placement of a prosthetic mesh. The most popular version was the Shouldice technique, initially introduced in 1958, and in essence a modification of the Bassini operation. This technique involves meticulous dissection of the entire inguinal floor and closure of the inguinal canal in four layers. The transversalis fascial layer itself is closed in two layers, as opposed to the single layer of interrupted suture advocated by Bassini. While the operation can be technically challenging to the beginner, it has been associated with excellent long-term outcomes and low recurrence rates.

Today, laparoscopic techniques have been validated as safe and effective in the treatment of groin hernias and have become commonplace. The laparoscopic approaches were initially developed in the early 1990s as laparoscopic techniques diffused throughout other specialties of general surgery.

Fig. 1 EXAMINATION IN INGUINAL HERNIA

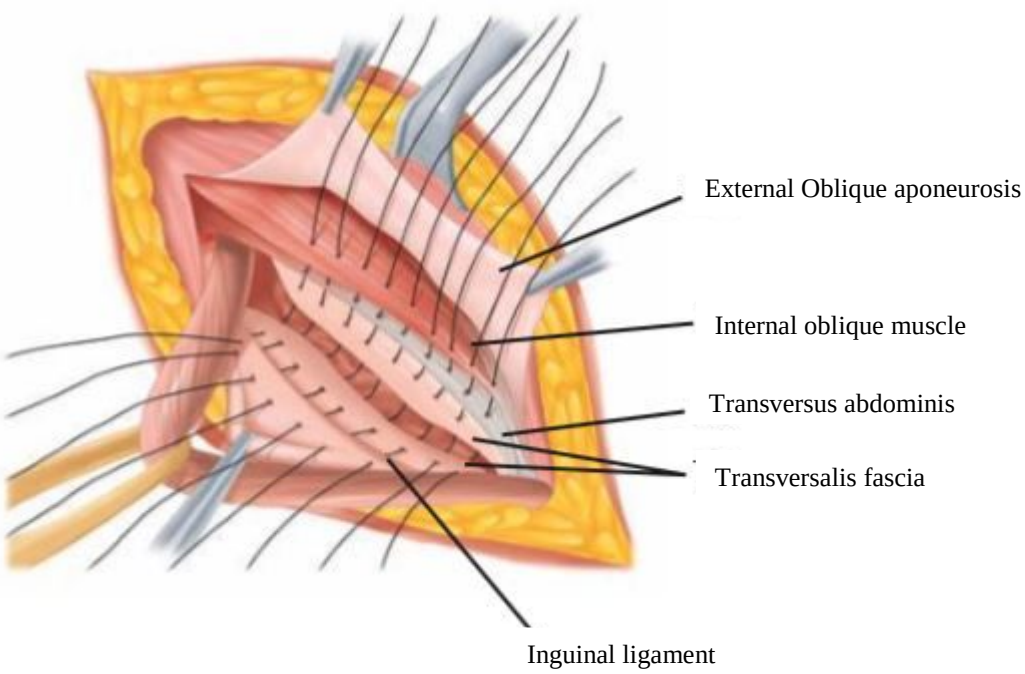


Fig. 2 MODIFIED BASSINI REPAIR

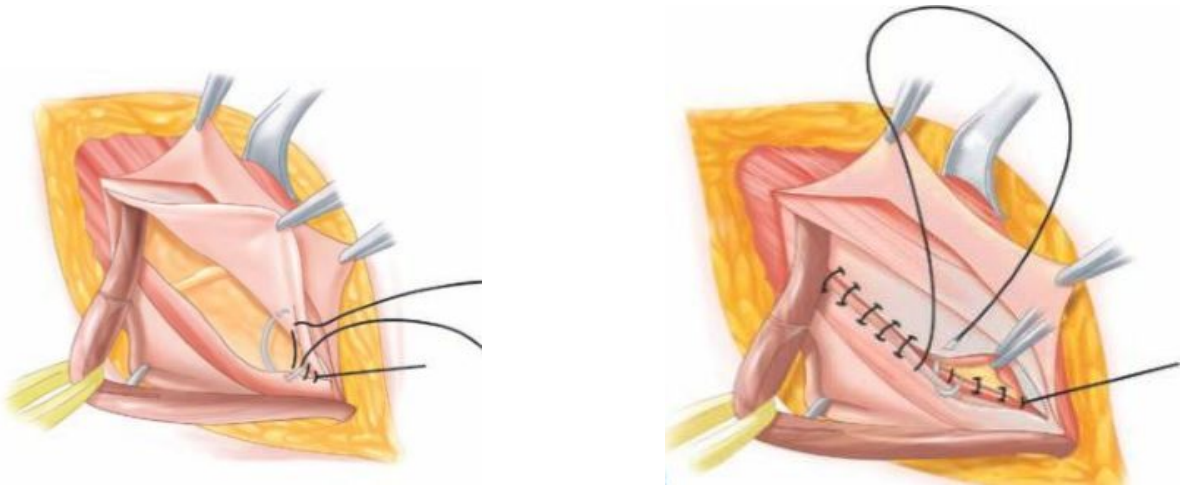


Fig.3 SHOULDICE REPAIR

ANATOMY

Layers of the Abdominal Wall in the Inguinal Region[11]:

1. Skin

2. Fascia Camper (fatty layer) and Fascia Scarpa (membranous layer).

3. Gallaudet's Fascia (Innominate fascia). This fascia is not recognized as a distinct entity. It is of no surgical importance. It constitutes the formation of the external spermatic fascia.

4. External oblique aponeurosis, the inguinal ligament, lacunar ligament, and reflected part of inguinal ligament.

5. Spermatic cord

6. Transversus abdominis muscle and its aponeurosis, internal oblique muscle fibres, falx inguinalis (Henle), and the conjoined tendon. We agree with McVay that the inguinal part of the transversus abdominis muscle originates from the iliopsoas fascia and not from the inguinal ligament. The muscle inserts into the pectineal (Cooper's) ligament.

7. Transversalis fascia – Anterior and Posterior lamina

8. Preperitoneal pad of fat with connective tissue.

9. Peritoneum

Bony Elements Related to the Inguinal Area

Those parts of the pelvis and the pelvic brim related to the soft parts of the inguinofemoral area are:

1) Iliopectineal line
2) Pubic tubercle
3) Symphysis pubis

The iliopectineal line and the arcuate line form the terminal line (linea terminalis) of the pelvis. The iliopectineal line of the pubic bone and the pubic crest creates the anterior part; the arcuate line of the ileum makes up the posterior part.

The terminal line extends from the promontory of the sacrum to the pubic symphysis. The following picture shows the relations of the Inguinal Region.

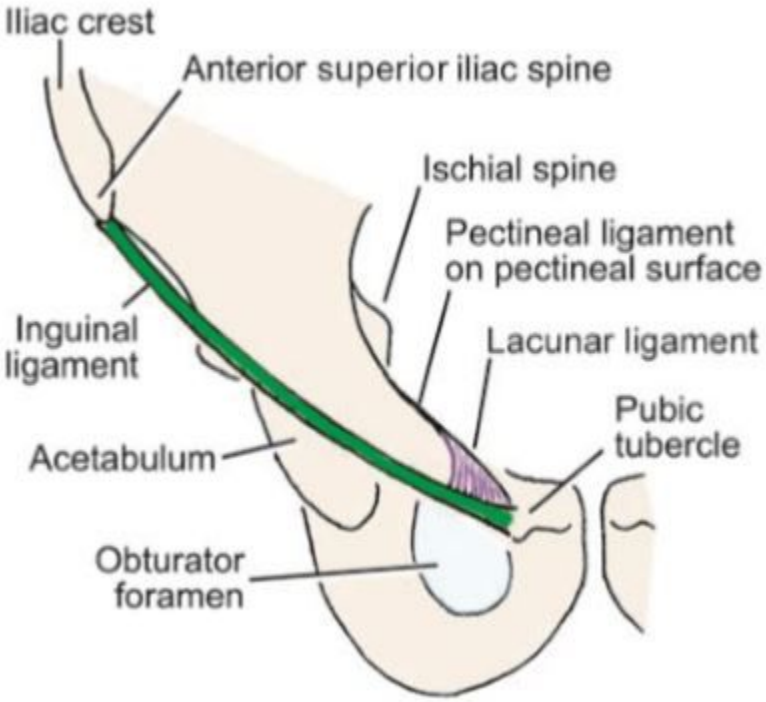


Fig.4 Bony Elements in relation to Inguinal Canal

Blood Supply of the Inguinal Area

Arteries

The blood supply to the inguinal area is very rich. It is divided into a superficial part for the subcutaneous fat and a deeper part for the musculoaponeurotic components.

The superficial branches of femoral artery help supply the abdominal wall below the umbilicus, giving off rami that pass upward in the subcutaneous connective tissue. From lateral to medial they are:

a) Superficial circumflex iliac artery (close to the iliac crest)

b) Superficial epigastric artery (at the midgroin area, with an upward vertical orientation)

c) Superficial external pudendal artery (inferior to inguinal ligament at fossa ovalis)

The superficial epigastric artery anastomoses with the contralateral artery, and they anastomose with the deep arteries.

Deep arteries lie between the internal oblique and transversus abdominis muscles. They are:

a) 10th and 11th posterior intercostal arteries
b) Anterior branch of the subcostal artery
c) Anterior branches of the four lumbar arteries
d) Ascending branch of the deep circumflex iliac artery

The blood supply to the rectus sheath is from the superior and inferior epigastric arteries, which frequently anastomose. The inferior epigastric artery enters the rectus sheath at or about the semicircular line of Douglas (arcuate line), between the rectus muscle and the posterior lamina of the sheath. The deep arterial network of the abdominal wall is composed of the inferior epigastric artery and the deep circumflex iliac artery. Both originate from the distal part of the external iliac artery.

The inferior epigastric artery gives off two branches:

a) External spermatic (cremasteric), which becomes part of the spermatic cord
b) Pubic, which crosses the ligament of Cooper and anastomoses with the obturator artery to occasionally become the aberrant obturator artery.

The deep circumflex iliac artery is located outside the preperitoneal space, deep to the iliopsoas fascia, close to the iliopectineal arch. From its origin, the deep circumflex iliac artery passes laterally, at first deep to the fascia iliaca and then beneath the iliopubic tract.

Its ascending branch passes upward vertically, just medial to the anterior superior iliac spine and between the transversus and internal oblique muscles. In laparoscopic herniorrhaphy, the deep circumflex iliac artery is subject to injury by staples or suture placement in anchoring mesh prostheses, and results occasionally in the formation of a hematoma.

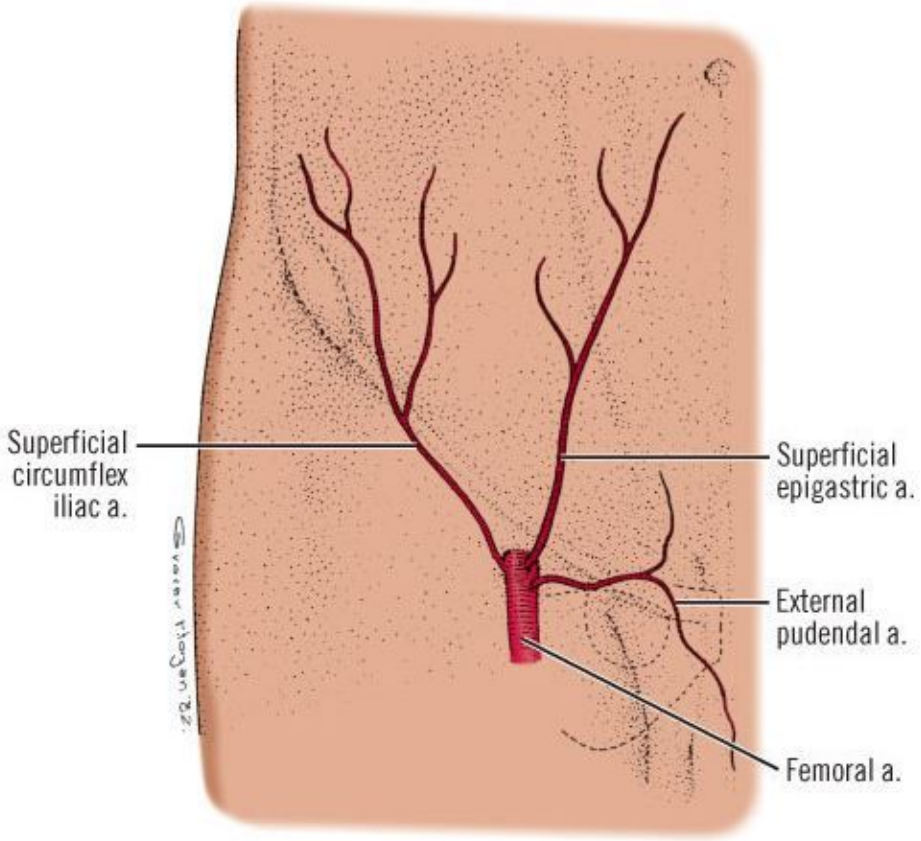


Fig. 5 (a) Blood Supply of Inguinal Region

Veins

The veins follow the arteries. The inferior epigastric veins and the deep circumflex iliac veins, two for each artery, empty into the external iliac vein.

Nerve Supply of the Inguinal Area[12]:

After leaving the superficial inguinal ring, the ilioinguinal nerve subdivides into:

1) large anterior scrotal or labial branches

2) a small pubic branch to the lower pubic area and the base of the penis or clitoris

3) crural branches to the upper inner thigh and inguinal crease.

The ilioinguinal nerve originated from the lumbar plexus independently and was formed by one root usually L1 rarely L2. The ilioinguinal nerve passes within the abdominal wall, above the iliac crest, deep to the internal oblique to a point just medial to the anterior superior iliac spine, at which point it becomes visible between the external and internal obliques and then passes into the inguinal canal.

The genitofemoral nerve typically divides into a femoral (lumboinguinal) branch and a genital (external spermatic) branch. The femoral branch passes in the femoral sheath beneath the inguinal ligament, ventral or lateral to the femoral artery, and supplies the skin of the thigh in the vicinity of Scarpa's (femoral) triangle. The genital branch exits the abdomen in the inferomedial angle of the deep ring, in

company with the cremasteric branches of the inferior epigastric vessels. Lying deep to the cremaster, it supplies that muscle and some of the skin of the scrotum.

Within the deep inguinal ring the genital branch is deep medially, with the cremasteric vessels; i.e., medial in such a way that the suturing of the crura of the internal ring is above and superficial to the position of the nerve.

Therefore, entrapment of the genital branch of the genitofemoral nerve at the deep ring should occur very rarely - perhaps just in those unusual cases in which the genital branch and the ilioinguinal nerves are combined and therefore located more superficially.

Leaving the deep inguinal ring, the genital branch is located at the lower margin of the iliopubic tract, together with the cremasteric vessels. Entrapment and injury of the nerve can take place only with deep suturing of the iliopubic tract.

The surgeon should also be careful not to injure the following three nerves: lateral femoral cutaneous, femoral, and anterior femoral cutaneous (a frequent variation).

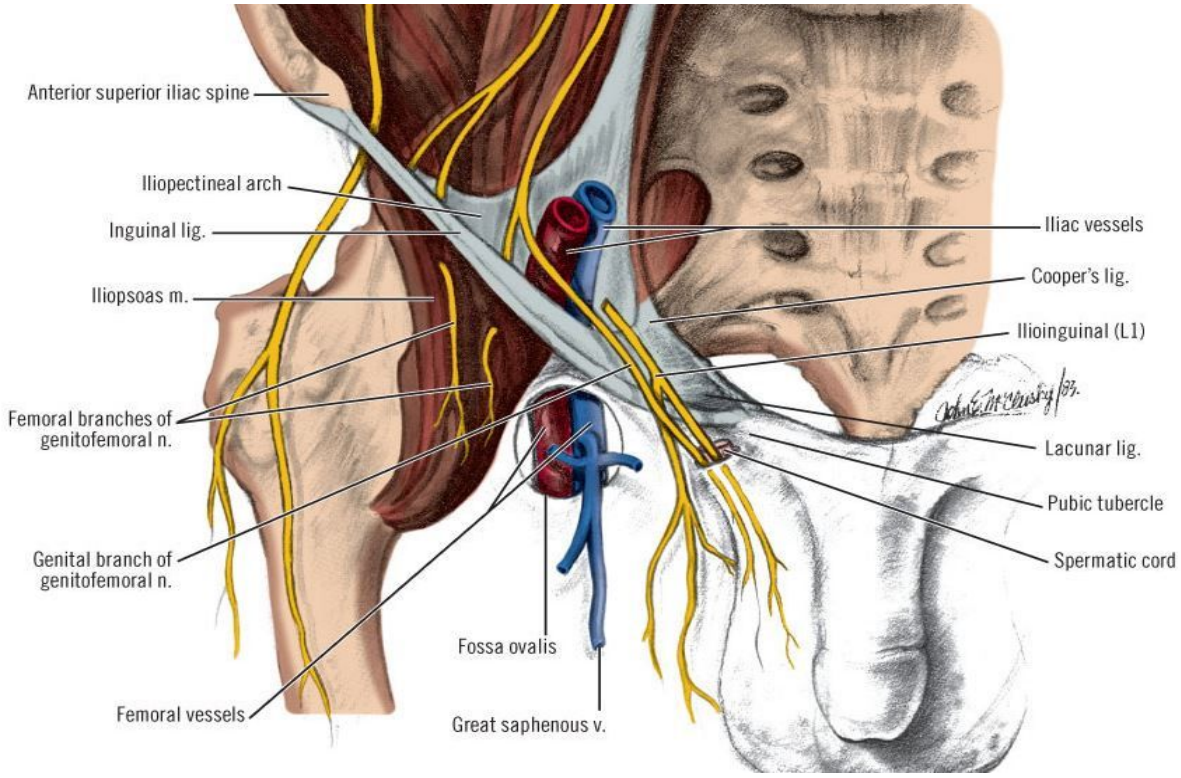
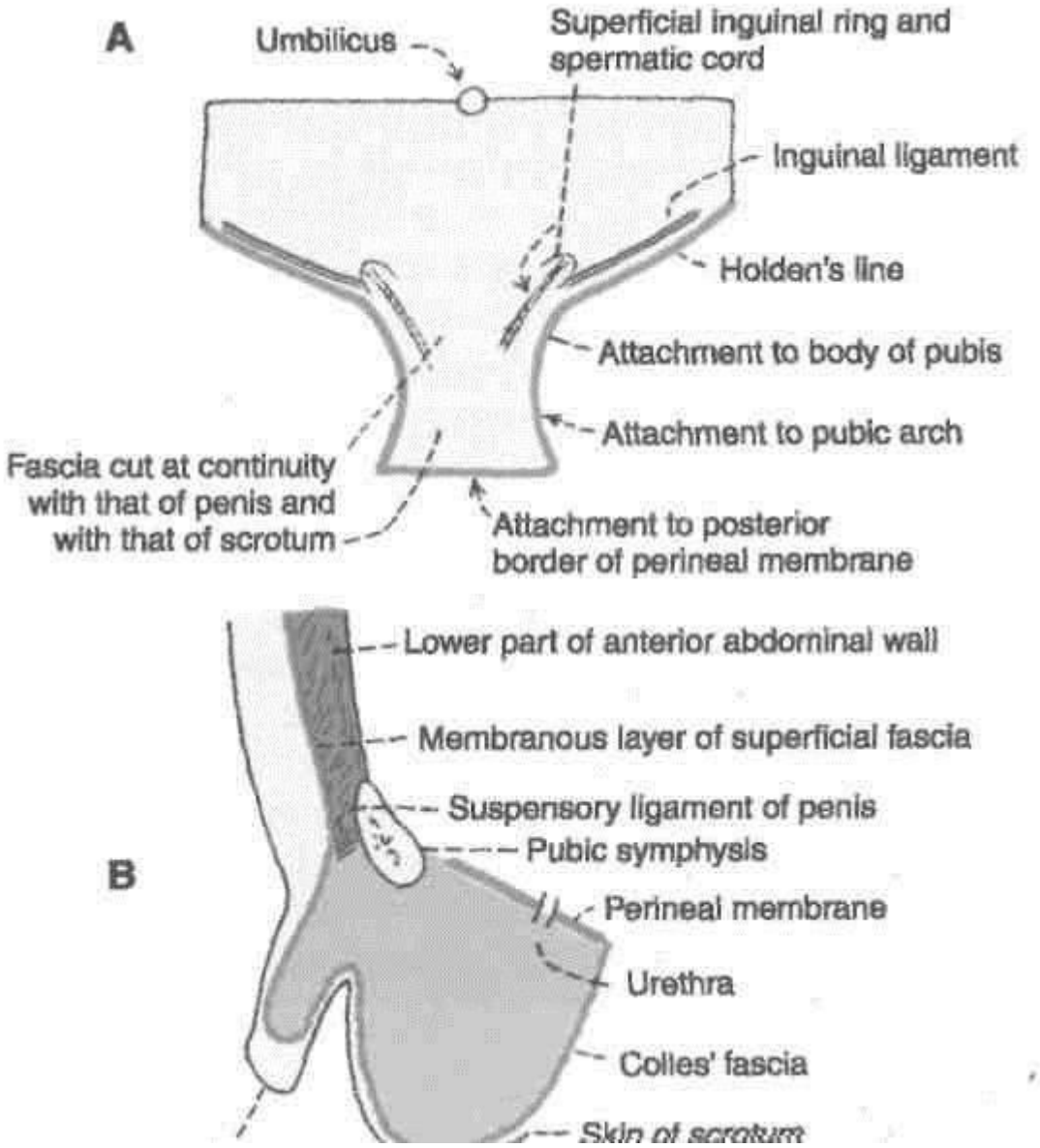


Fig 5 (b) Anatomy of nerve supply of Inguinal Region



The extent and attachments of the superficial fascia of the abdomen and perineum in a male. (A) Anterior view; (B) in sagittal section.

The veins runs together with the arteries. Superficial inguinal veins drain into the great saphenous vein.

LYMPHATIC DRAINAGE

Above the level of the umbilicus the lymphatics run upwards to drain into the axillary lymph nodes. Below the level of the umbilicus they run downwards to drain into the superficial inguinal lymph nodes.

MUSCULATURE OF ANTERIOR ABDOMINAL WALL

The anterior abdominal wall is mainly made of muscles. There are four large muscles on either side of the midline. These are the external oblique, the internal oblique, the transversus abdominis and the rectus abdominis.

the cremaster and the pyramidalis are the other two that are present. The large flat muscles, the external oblique, the internal oblique and the transversus abdominis are placed in the anterolateral part of the abdominal wall. Each of them ends in an extensive aponeurosis which reach the midline. Here the aponeuroses on either side decussate to form a median band called the linea alba.

The rectus abdominis runs vertically on either side of the linea alba. It is enclosed in a sheath formed by the aponeuroses of the flat muscles named above.

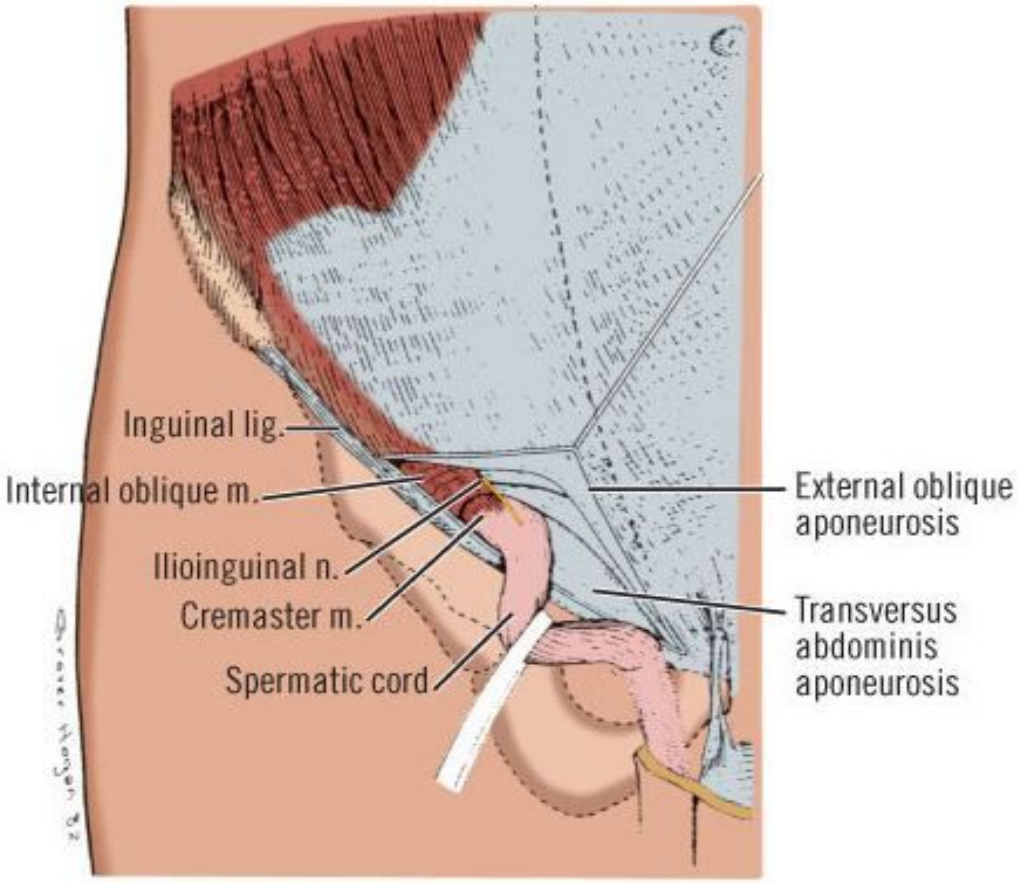


Fig.6 Musculature of Anterior Abdominal Wall

External Oblique Muscle

Origin –from middle of lower eight ribs

Then run downwards, forwards and medially

Insertion -

1. Most of the fibres of the muscle end in a broad aponeurosis through which they are inserted from above downwards into the xiphoid process, the linea alba, the pubic symphysis, the pubic crest and the pectineal line of the pubis

2. The lower fibres of the muscle are inserted directly onto the anterior two thirds of the outer lip of the iliac crest.

Nerve Supply - Lower six thoracic nerves.

Internal Oblique Muscle

Origin

The muscle arises from :

a. The lateral two-thirds of the inguinal ligament .

b. The anterior two-thirds of the intermediate area of the iliac crest, and

c. The thoracolumbar fascia

From this origin the fibres run upwards, forwards and medially crossing the fibres of the external oblique muscle at right angles.

Insertion

1. The uppermost fibres are inserted directly into the lower three or four ribs and their cartilages.
2. The greater part of the muscle ends in an aponeurosis through which it is inserted into the seventh, eighth and ninth costal cartilages, the xiphoid process, the linea alba, the pubic crest and the pectineal line of the pubis.

Nerve Supply

Lower six thoracic nerves and the first lumbar nerve.

Transversus Abdominis Muscle

Origin

The muscle has a fleshy origin from :

a. The lateral one-third of the inguinal ligament.

b. The anterior two-thirds of the inner lip of the Iliac crest.

c. The thoracolumbar fascia

d. The inner surfaces of the lower six costal cartilages. The fibres are directed horizontally forwards.

Insertion

The fibres end in a broad aponeurosis which is inserted into the xiphoid process, the linea alba, the pubic crest, and the pectineal line of the pubis. The lower most fibres of the muscle fuse with the lower fibres of the internal oblique to form the conjoint tendon.

Nerve Supply

Lower six thoracic nerves, and first lumbar nerve.

Rectus Abdominis Muscle

Origin

The muscle arises by two tendinous heads as follows:

a. Lateral head from the lateral part of the pubic crest.

b. Medial head from the anterior pubic ligament. The fibres run vertically upwards.

Insertion

On the front of the wall of the thorax, along a horizontal line passing laterally from the xiphoid process, and cutting in that order, the 7th, 6th and 5th costal cartilages.

Nerve Supply

Lower six or seven thoracic nerves.

Inguinal Ligament

1. Lower margin of external oblique aponeurosis becomes thick and turns back to form the inguinal ligament

Extension- anterior superior iliac spine to the pubic tubercle.

It lies beneath the fold of the groin. Its lateral half is oblique and rounded. Its medial half is more horizontal and grooved upwards.

2. *Attachments :* (a) The fascia lata is attached to its lower border. Traction of this fascia makes the ligament convex downwards, (b) The upper surface of the ligament gives origin to the internal oblique from its lateral two-thirds, to the transversus abdominis from its lateral one-third, and to the cremaster muscle from its middle part.

3. *Relations* : The upper grooved surface of the medial half of the inguinal ligament forms the floor of the inguinal canal and lodges the spermatic cord in males and round ligament of the uterus in females.

Conjoint Tendon or Falx Inguinalis:

The conjoint tendon is formed by the fusion of lower aponeurotic fibres of internal oblique and transversus abdominis *muscle, which is attached* to the to the medial part of the pecten pubis and pubc crest. *Anterior wall of the* rectus sheath forms the medial continuation of it. Laterally, it is usually free. Sometimes it may be continuous with an inconstant ligamentous band, named the interfoveolar ligament, which contracts the lower border of the transversus abdominis to the superior ramus of the pubis. The conjoint tendon strengthens the abdominal wall at the site where it is *weakened* by *the* superficial inguinal ring.

The Cremaster Muscle

The Cremaster muscle consists of muscle fasciculi embedded in the Cremasteric fascia. The fasciculi form loops that are attached laterally to the inguinal ligament. Here some fibres may be continuous with the internal oblique

or transversus muscles. The medial ends of the loops are attached to the pubic tubercle, the pubic crest or the conjoint tendon. The muscle is fully developed only in the male. In the female it is represented by a few fibres only.

Along with the intervening connective tissue, the muscle loops to form a sac like cremasteric fascia around the spermatic cord and testis. It lies deep to the external spermatic fascia.

Nerve Supply (Genital branch of the genitofemoral nerve [L1])

Action

The testis is suspended by the cremaster which can elevate it. The muscle also tends to close the superficial inguinal ring when the intra-abdominal pressure is raised.

Cremasteric Reflex

Upon stroking the skin of the upper part of the medial thigh, there is contraction of the cremaster muscle, as evidenced by elevation and retraction of the testis. The reflex is more brisk in I children. In upper motor neuron lesions above segment L1, the reflex is lost.

FASCIA TRANSVERSALIS

Definition

The fascia that lies beneath the transverse abdominis is called fascia transversalis.

Extent

Anteriorly - adherent to the linea alba above the umbilicus.

Posteriorly - merges with the anterior layer of the thoracolumbar fascia

Superiorly - continuous with the diaphragmatic fascia.

Inferiorly - attached to the inner lip of the iliac crest and to the lateral half of the inguinal ligament, where it is continuous with the fascia iliaca;

Medially - attached to pubic tubercle, pubic crest and the pectineal line and partly prolongs into the thigh as the anterior wall of the femoral sheath.

Opening of Deep Inguinal Ring

An oval opening is felt about 1.2 cm above the mid inguinal point in the fascia transversalis, which is the deep inguinal ring. It lies immediately lateral to the inferior epigastric artery. It transmits the spermatic cord in males, and the round ligament of the uterus in females.

Prolongations

1. Internal Spermatic Fascia - A tubular prolongation of the fascia transversalis surrounding the spermatic cord.
2. Anterior Wall Of Femoral Sheath – Prolongs into the thigh over the femoral vessels.

Relation to Vessels and Nerves

The main arteries of the abdominal wall and pelvis lie inside the fascia transversalis, while the main nerves are outside. That is why the femoral vessels are inside the femoral sheath, while the femoral nerve is outside the sheath.

INGUINAL CANAL

Definition

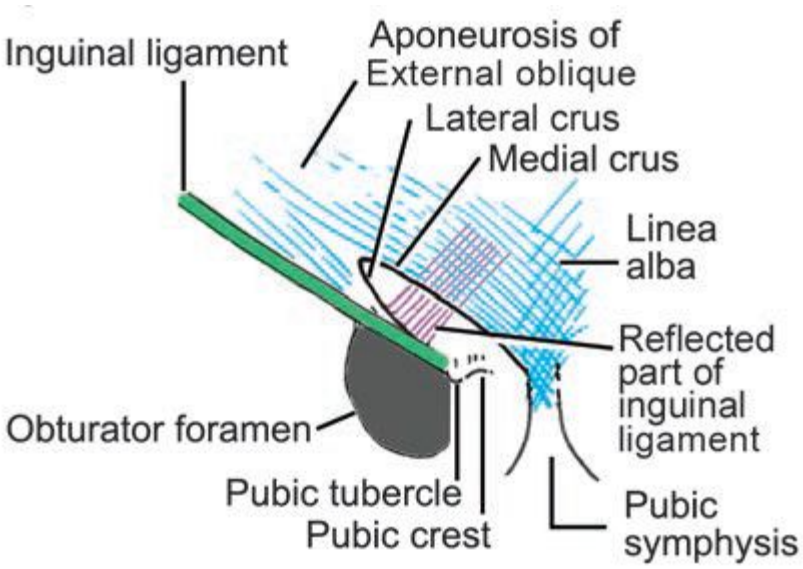
Its an oblique canal that is present above the medial half of the inguinal ligament.

Length and direction: It is about 3.5 cm to 4 cm and is directed forwards, medially and downwards.

Extension- extends from the deep inguinal ring to the superficial inguinal ring

DEVELOPMENT OF INGUINAL CANAL

Inguinal canal represents the passage of *guberna-culum* through the abdominal wall; it extends from the caudal end of the developing gonad (in lumbar region) to the *labioscrotal swelling.* In early life, the canal is very short. As the pelvis increases in width, the deep inguinal ring is shifted laterally and the adult dimensions of the canal are attained.



Superficial inguinal ring.

Sex Difference

Larger Inguinal canal in males when compared to females

Structures Passing through the Canal

1. *Males* – Spermatic cord, *Females* – Round ligament.

2. The ilioinguinal nerve

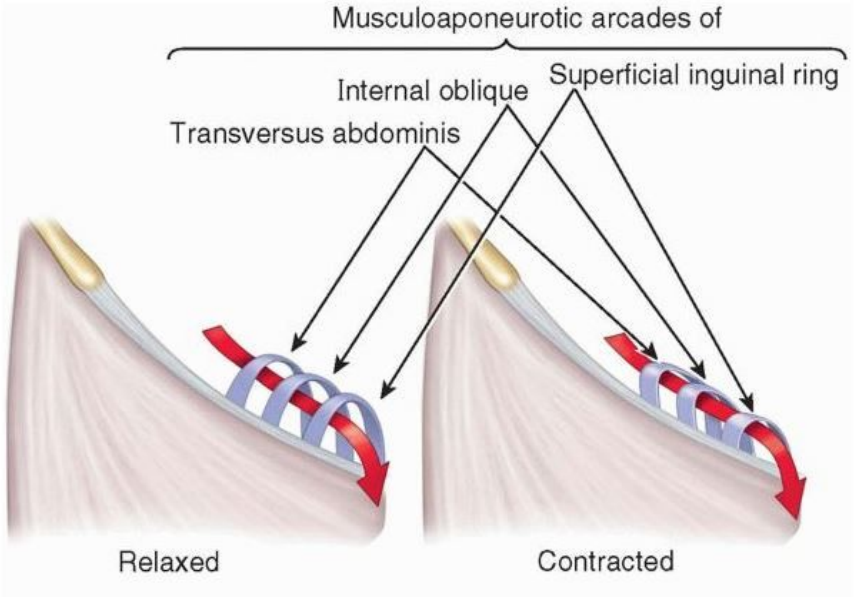
Mechanism of Inguinal Canal

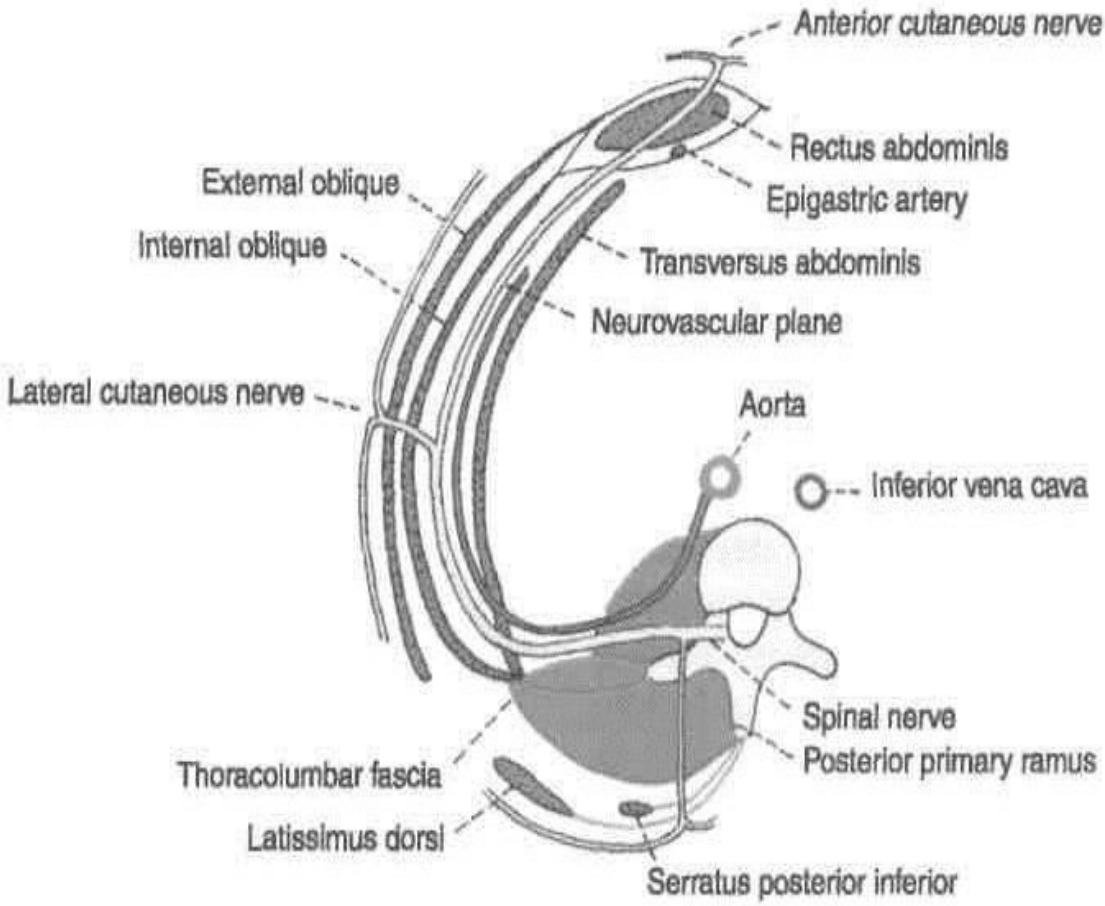
The presence of the inguinal canal is a cause of weakness in the lower part of the anterior abdominal wall. This weakness is compensated by the following factors.

1. **Obliquity of the inguinal canal:** The two inguinal rings do not lie opposite each other. Therefore, when the intra-abdominal pressure rises the anterior and posterior walls of the canal are approximated, thus obliterating the passage. This is known as the flap valve mechanism.
2. The superficial inguinal ring is guarded from behind by the conjoint tendon and by the reflected part of the inguinal ligament.
3. The deep inguinal ring is guarded from the front by the fleshy fibres of the internal oblique.
4. **Shutter mechanism of the internal oblique:** This muscle has a triple relation to the inguinal canal. It forms the anterior wall, the roof, and the posterior wall of the canal. When it contracts the roof is approximated to the floor, like a shutter. The arching fibres of the transversus also take part in the shutter mechanism.

5. Contraction of the cremaster helps the spermatic cord to plug the superficial inguinal ring (ball valve mechanism).
6. Contraction of the external oblique results in approximation of the two crura of the superficial inguinal ring (slit valve mechanism). The integrity of the superficial inguinal ring is greatly increased by the intercrural fibres.
7. Hormones may play a role in maintaining the tone of the inguinal musculature.

Whenever there is a rise in intra-abdominal pressure as in coughing, sneezing, lifting heavy weights all these mechanisms come into play, so that the inguinal canal is obliterated, its openings are closed, and herniation of abdominal viscera is prevented.





Transverse section through the lumbar region showing the abdominal wall musculature and neurovascular plane

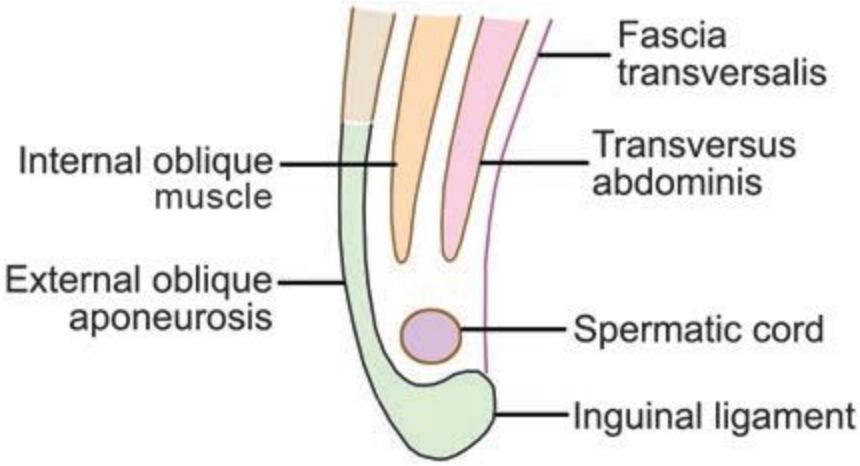


Fig. 8 (a) Boundaries of the inguinal canal:

A) Anterior and posterior walls in horizontal section

B) Roof and floor in sagittal section

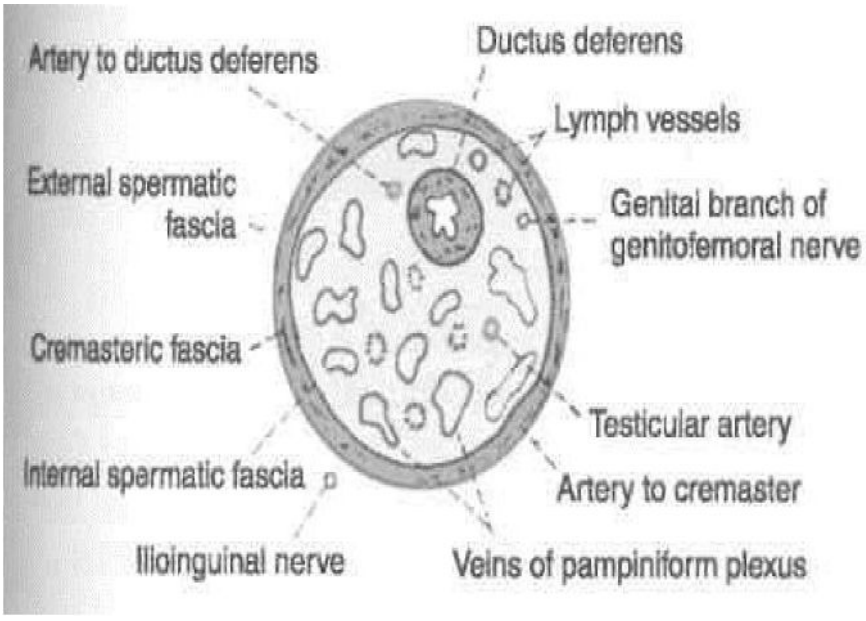
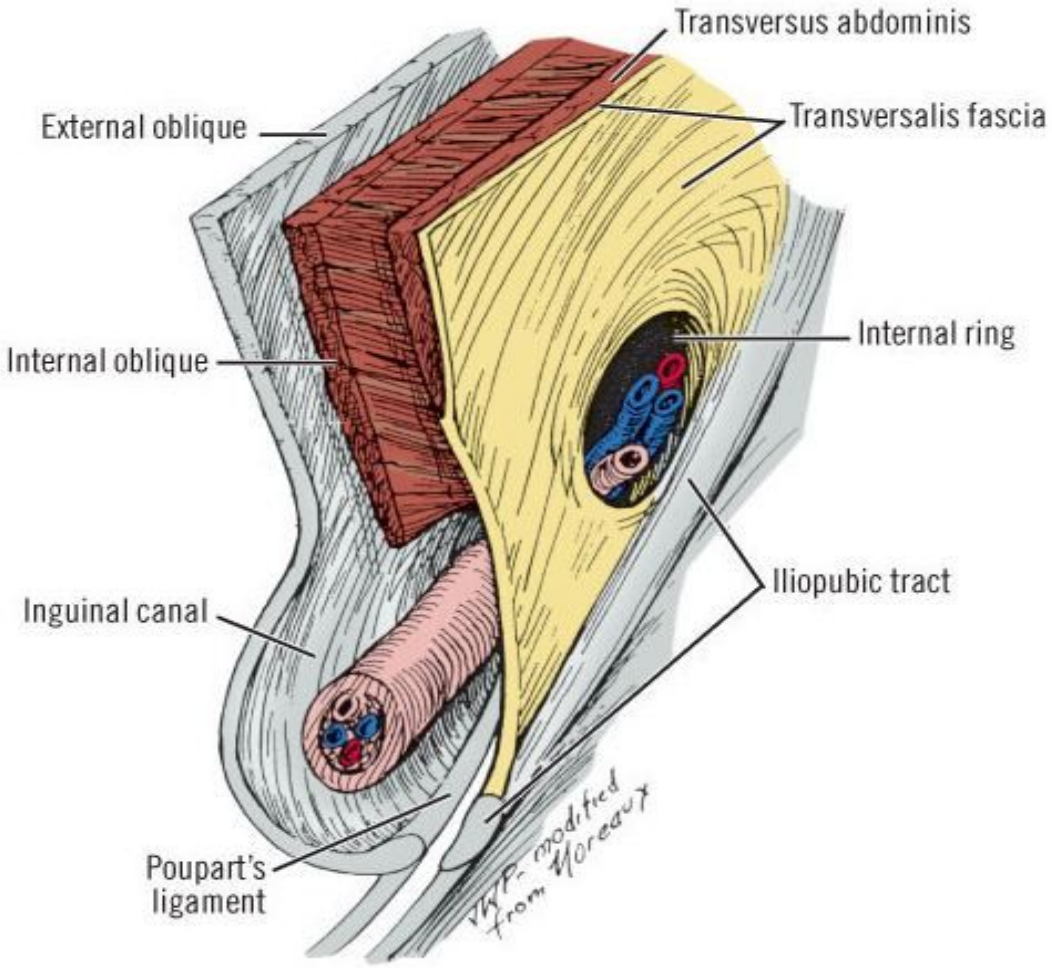


Fig.8 (b) Contents of the spermatic cord



BOUNDARIES OF INGUINAL CANAL

Hesselbach's triangle[13] – Direct inguinal hernia occurs through the weaker part of anterior abdominal wall known as Hesselbach's triangle .

Boundaries are

1) Medial border - lateral margin of rectus abdominis muscle.
2) Lateral border - inferior epigastric artery and vein.
3) Inferior border - medial part of inguinal ligament.

The floor of the Hesselbach's triangle is formed by the Fascia transversalis.

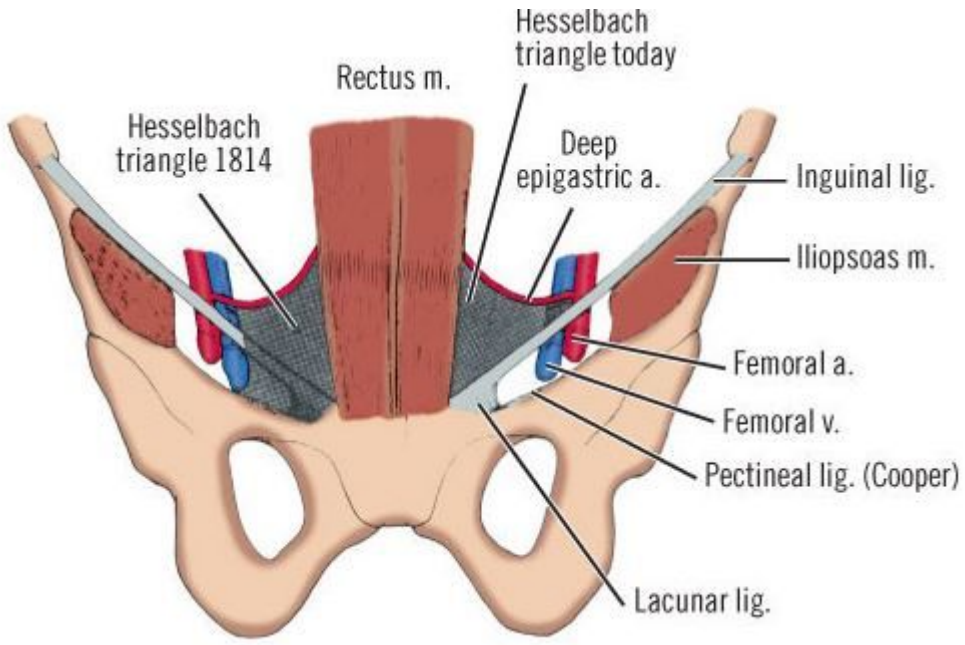


Fig.9 Surgical anatomy of Hesselbach's triangle

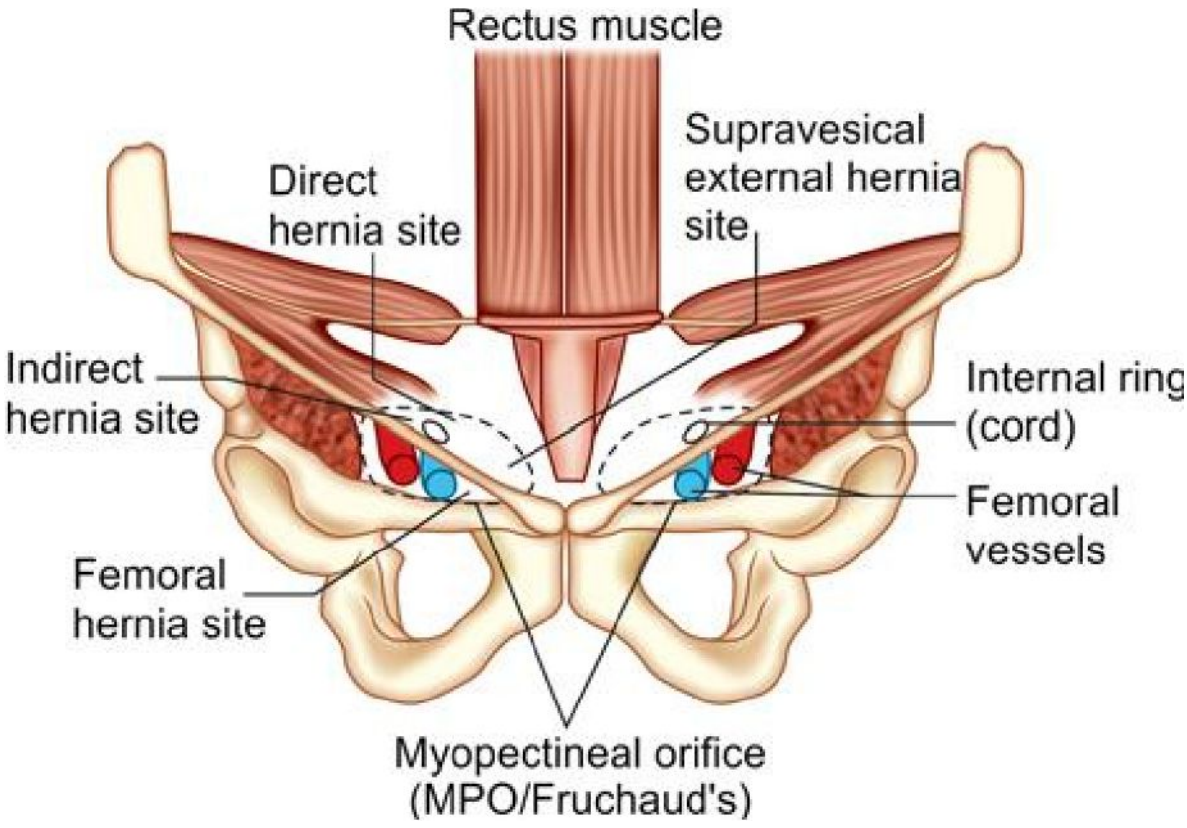


Fig.10 Surgical anatomy of myopectineal orifice

CLASSIFICATION OF INGUINAL HERNIA

(EARLIER)

Classification I

Anatomical Classifi cation (in Inguinal Hernia)

Indirect hernia

It comes out through internal ring along with the cord. It is lateral to the inferior epigastric artery.

Direct hernia

It occurs through the posterior wall of the inguinal canal through 'Hesselbach's triangle' Sac is medial to the inferior epigastric artery.

Classification-II According to the Extent

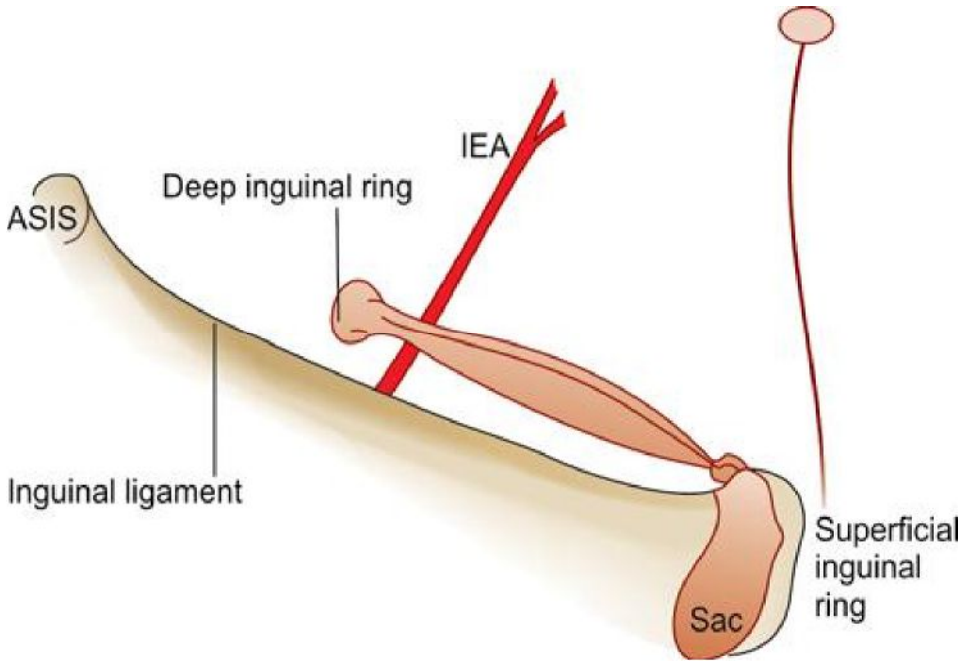
Incomplete:

Bubonocele: Here sac is confined to the inguinal canal.

Funicular: Here sac crosses the superficial inguinal ring.

Complete:

Here sac reaches the lower part of the scrotum. Saddle-bag or pantaloon hernial sac has got both medial and lateral component.

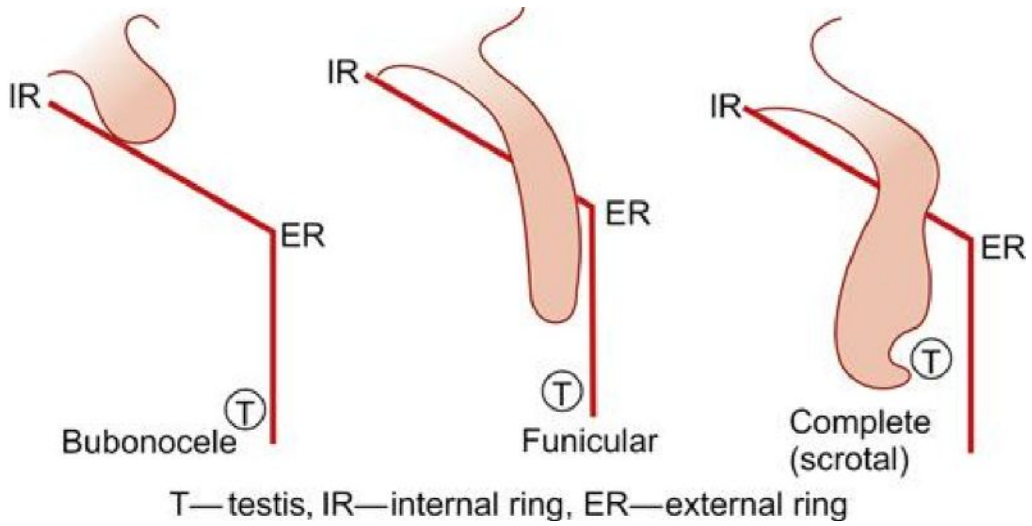


Surgical anatomy of indirect inguinal hernia

Types

Three types

1. ***Bubonocele***: Where the hernia is limited to inguinal canal.
2. ***Funicular:*** Processus vaginalis is closed just above the epididymis. Below the hernia, the contents of the sac can be felt separately from testis.
3. ***Complete (Scrotal*)**: The lower part of hernia appears to encompass the testis. It can occur in any age group. It occurs in a congenital preformed sac (processus vaginalis). More commonly contents descend into the pre-existing sac, only when there are precipi tating causes which force the content down.



Types of indirect inguinal hernia.

OTHER SYSTEMS OF CLASSIFICATION:

GILBERT's CLASSIFICATION:

***Type I*:** Hernia has got snug internal ring through which a peritoneal sac passes out as indirect sac.

Type II: Hernia has a moderately enlarged internal ring which admits one finger but lesser than two finger breadth. Once reduced it protrude during coughing or straining.

Type III: Hernia has got large internal ring with defect more than two finger breadth. Hernia descends into the scrotum or with sliding hernia. Once reduced it immediately protrudes out without any straining.

Type IV: It is direct hernia with large full blow out of the posterior wall of the inguinal canal. The internal ring is intact.

Type V: It is a direct hernia protruding out through punched out hole/defect in the transversalis fascia. The internal ring is intact.

Type VI: Pantaloon/double hernia.

Type VII: Femoral hernia.

Type VI and VII are Robbin's modifications.

NYHUS CLASSIFICATION

Type I: Indirect hernia with normal deep ring.
Type II: Indirect hernia with dilated deep ring.
Type III: Posterior wall defect.

a. Direct.
b. Pantaloon hernia.
c. Femoral hernia.

Type IV: Recurrent hernia.

BENDAVID CLASSIFICATION:

Type I: Anterolateral defect (indirect).
Type II: Anteromedial (direct).
Type III: Posteromedial (femoral).
Type IV: Posterior prevascular hernia.
Type V: Anteroposterior defect: Inguino-femoral hernia.

CASTEN's CLASSIFICATION:

Stage 1: An indirect hernia with a normal internal ring.
Stage 2: An indirect hernia with enlarged internal ring.
Stage 3: All direct or femoral hernias.

HALVERSON AND McVAY CLASSIFICATION:

Class 1: Small indirect hernia.
Class 2: Medium indirect sac.
Class 3: Large indirect hernia or direct hernia.
Class 4: Femoral hernia.

DIFFERENTIAL DIAGNOSIS OF GROIN HERNIA:

1) Enlarged lymph nodes
2) Undescended Testis
3) Lipoma
4) Femoral Hernia
5) Saphena Varix
6) Psoas abscess
7) Femoral artery aneurysm / Pseudoaneurysm
8) Encysted hydrocele of cord
9) Varicocoele
10) Epididymitis
11) Sebaceous cyst
12) Hematoma
13) Ascites

HERNIOPLASTY

Lichtenstein introduced the tension free hernioplasty in 1984.

It is ideally, herniotomy followed by the reinforcement of posterior wall of the inguinal canal by bridging the gap between the conjoined tendon and inguinal ligament by either autogenous material or heterogeneous material.

Indications of hernioplasty -

1) indirect hernia- with decreased muscle tone

2) direct hernia

3) recurrent hernias

(1) LICHTENSTEIN TENSION FREE HERNIOPLASTY

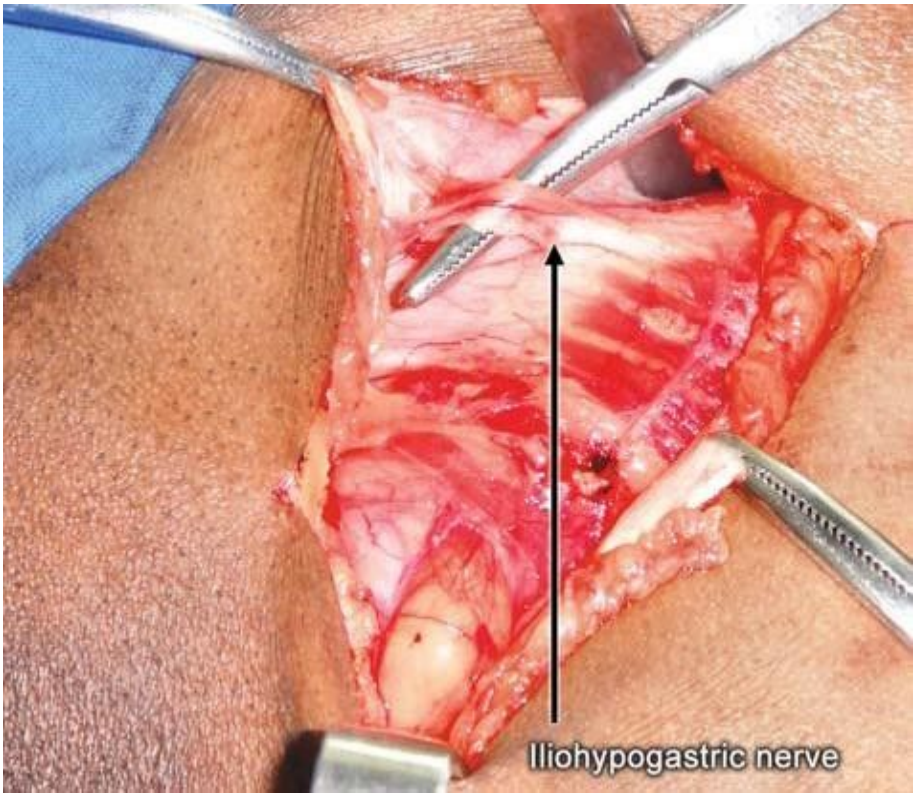
OPERATIVE PROCEDURE

An incision is made 1.25 cm above and parallel to inguinal ligament extending from pubic tubercle upto 1 cm lateral to mid point of inguinal ligament.skin, subcutaneous tissue, external oblique aponeurosis opened in layers.Cremaster, cremastric fascia, internal spermatic fascia opened.Indirect sac is identified anterolateral to the cord, and dissected from the cord structures.Indirect sac opened and contents reduced. Sac is ligated at the level of neck with excision of excess sac. Lytle's repair done.

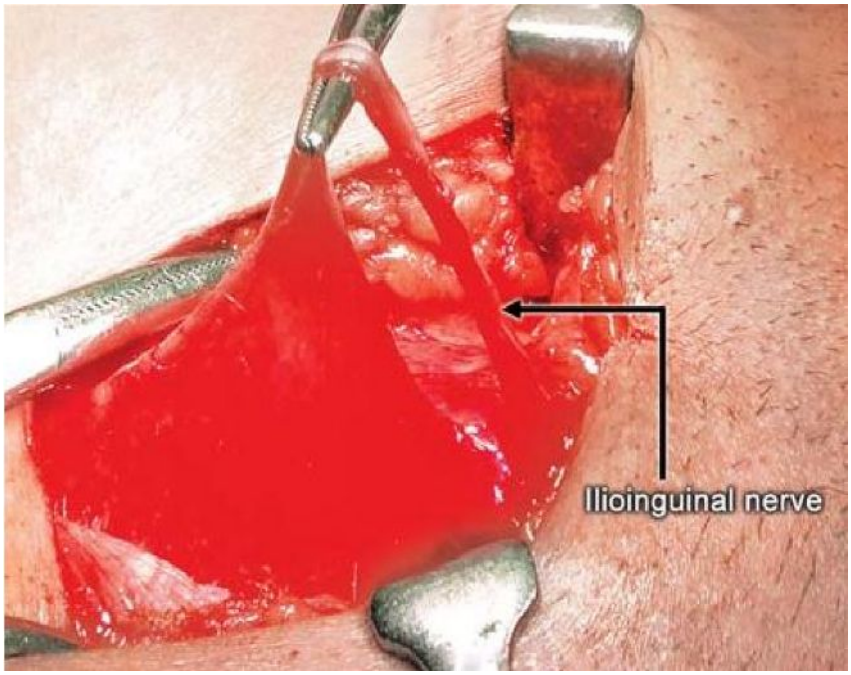
If there is direct hernia, the sac is reduced by taking bites from the transversalis fascia with absorbable sutures.

Non absorbable Mesh of size 6 x11 cm is placed over the posterior wall by taking bites from the pubic tubercle, inverted portion of inguinal ligament,conjoint tendon with non absorbable sutures.Wound is closed in layers.Sterile dressing applied.scrotal bandage applied.

(a) Incision



(b) Iliohypogastric nerve



(c)

(d)

Ilioinguinal nerve and the hernia sac being opened

(e)

Fig.11 (a-e) LICHTENSTEIN's HERNIOPLASTY

COMPLICATIONS OF INGUINAL HERNIA REPAIR

(I) Wound infection

- Incidence <1%
- It is in the form of seroma, pus discharge, hematomas

Clinical presentation

– Fever, pain and inflammatory signs around infected area.

Treatment :

1) drainage of pus – if infection is localized
2) If there is extensive area of infection- requires opening of wound/debridement with antibiotics depending on culture sensitivity

II) Recurrence:

- Recurrence in early period is rare
- Often due to secondary infection, undue tension on repair, tissue ischaemia/ overactive patient in immediate postoperative period
- Larger hernias
- Smoking

III) Complications involving vas deferens

a. Dysejaculation syndrome

b. Transection of vas

IV) Neuralgia:

- Follows distribution of Ilioinguinal nerve, iliohypogastric nerve, genital branch of genito femoral nerve
- Often due to nerve entrapment

V) Damage to blood vessels of testicles

VI) Ischemic orchitis and testicular atrophy

VII) Testicular pain

VISUAL ANALOG SCALE:

It is a measure of pain intensity[15], used in diverse adult populations[16–19].

The pain VAS is a continuous scale comprising a horizontal line, usually 10 centimeters in length, which consists of verbal descriptors for each symptom[16,20]. The VAS is a single-item scale. The scale depicts a score of 0 for-"no pain" and a score of 10 for "worst imaginable pain"[20–22]. Most often patients are asked to report "current" pain intensity or pain intensity "in the last 24 hours."

The pain VAS is easily available and it is cost effective[21]. It can be completed by the patient himself. The respondent is asked to place a line perpendicular to the VAS line at the point that represents their pain intensity[16,23,24]. The VAS takes 1 minute to complete[17,21]. In postsurgical wards, patients describe their postoperative pain as none, mild, moderate, or severe based on the distribution of pain VAS scores. A higher score indicates greater pain intensity[17,21].

The VAS is administered using a paper and pencil, hence it is not possible to administer verbally or by phone. No specific training is required. One requires the ability to use a ruler to measure distance to determine a score[21,23]. Photocopying the

scale may change the length of the 10-cm line, so caution is required while doing so[20]. The pain VAS originated from continuous visual analog scales developed in

the field of psychology to measure the state of well-being[27,28]. Woodforde and Merskey[29] first reported use of the VAS pain scale using the descriptor extremes of "no pain at all" and "my pain is as bad as it could possibly be" in patients with a variety of illness.

The pain VAS requires little training to administer[16,24]. However, elderly patients may have difficulty understanding due to their cognitive impairment[20,30]. Reliability is higher among literate (r 0.94, P 0.001) than illiterate patients (r 0.71, P 0.001)[22]. For construct validity, the pain VAS has been highly correlated with a 5-point descriptive scale ("nil," "mild," "moderate," "severe," and "very severe") and a numeric scale (with response options from "no pain" to "unbearable pain"), with correlations ranging from 0.71–0.78 and 0.62–0.91, respectively[17].

The VAS is widely used due to its simplicity and adaptability to a broad range of populations and settings. Its acceptability as a generic pain measure was demonstrated in the early 1970s.

Limitations:

a) Due to cognitive impairments and motor skill issues, elderly patients may have difficulty in answering the pain VAS score sheet.

b) It cannot be administered by telephone.

c) It is more of a Subjective form of score.

Inguinal herniae are the most common of all anterior abdominal wall herniae[2]. Surgical treatment of the inguinal herniae has undergone tremendous transformation in the past few decades. The Lichtenstein tension-free repair is now considered the gold standard of hernia repair[4]. It has gained wide spread acceptance due to its superior outcome.

Regardless of the tension-free technique which appears painless, mild or moderate pain still exists and mesh alone may not be the only cause for this[1]. Due to the mechanical pressure and ischemic changes, ligation of the highly innervated peritoneal sac is a major cause of post-operative pain. It is speculated that non ligation does not increase the risk of recurrence and causes less postoperative pain[7].

Conventionally, Surgeons have long laboured under the burden of the ‘hernia sac’ in inguinal hernia. Thus the sac got pride of place in hernia surgery at the expense of the ‘defect’. It is a long held belief that ligation of the sac is an important adjunct to inguinal hernia operations[8].

Rutkow et al recommends that hernia sac should not be ligated, because peritoneum is a highly sensitive structure, ligating the sac does nothing more than producing a miniature ‘peritonitis’. This iatrogenic peritonitis is one of the factors contributing to the postoperative discomfort and pain that accompany suture hernia repairs[9].

High dissection and not high ligation is the critical factor. High ligation does not influence recurrence rate and may be a cause of increased post-operative pain[10].

The benefits of non-ligation of the sac has been investigated by Vincet et al. They found that non ligation does not increase the risk of recurrence and causes less post-operative pain[8]. However, high dissection of the sac well up into the retroperitoneum and freeing the sac from the edges of the internal ring are important for prevention of recurrence[8].

Deliloukos et al[1] in a study between January 1999 and December 2006, postoperative pain was associated with statistically significantly more episodes in people who underwent sac ligation, 27% than who did not undergo sac ligation, 9% which were statistically significant ($P \leq 0.05$), thereby there was a significant benefit from the exclusion of High hernia sac ligation on postoperative pain in patients who undergo tension-free indirect inguinal hernia mesh repair.

According to Balakh Sher Zaman et al[14], mean pain scores in patients underwent sac reduction were 3.30 ± 0.70 on 1st post op day, 2.22 ± 0.58 on 7th and 0.32 ± 0.47 on 10th post op day, while mean pain score in patients underwent high sac ligation was 4.34 ± 0.82 on 1st post op day, 3.34 ± 0.64 on 7th and 2.40 ± 0.53 on 10th post op day which shows that ligation of the hernia sac in inguinal hernia surgery is not only unnecessary and time consuming but also leads to increased post operative pain.

Encouraged by the studies of Abrahamson J[10] and Vincet et al[8] the present study is designed. The aim of the present study is to see the effects of sac reduction without ligation in indirect inguinal hernia repairs.

The focus is on post-operative pain. This study demonstrated less post-operative pain and hence decreased morbidity in patients undergoing sac reduction without ligation.

METHODOLOGY

PLACE OF STUDY:

DEPARTMENT OF GENERAL SURGERY, STANLEY MEDICAL COLLEGE AND HOSPITAL

DURATION:

OCTOBER 2014 TO SEPTEMBER 2015

STUDY DESIGN:

RANDOMIZED CONTROLLED STUDY

INCLUSION CRITERIA:

Clinically diagnosed patients of Indirect Inguinal Hernia of the Age group 20-60yrs.

EXCLUSION CRITERIA:

1) Patients with simultaneous direct & indirect hernia in the same groin,

2) Simultaneous bilateral indirect inguinal hernia,

3) Recurrent hernia, clinically irreducible hernia, sliding hernia, complete hernia.

4) Clinically strangulated hernia, congenital hernia and Diabetic patients.

Method of study:

- Sample size of 60 cases (30 in each group) is taken. An informed consent was obtained from them after discussion of risk versus benefit ratio. The study is Double blind.
- Patients were divided randomly in two equal groups. Group A included patients undergoing high sac ligation while Group B included sac reduction patients.
- All patients were operated under regional anaesthesia.
- In **Group A**, after confirming intraoperative diagnosis of indirect inguinal hernia, hernial sac opened, its contents returned to the peritoneal cavity, the excessive sac excised and **ligation of sac** performed using an absorbable suture (2'0 vicryl).
- In **Group B**, after confirming intraoperative diagnosis of indirect inguinal hernia, hernial sac is opened, its contents reduced and returned to peritoneal cavity **without ligation of the sac**.
- Lytle's repair(with 2'0 prolene) was done for all patients.

Later on in both groups Lichtenstein tension-free mesh repair was performed. Care is taken to avoid ilioinguinal nerve entrapment.

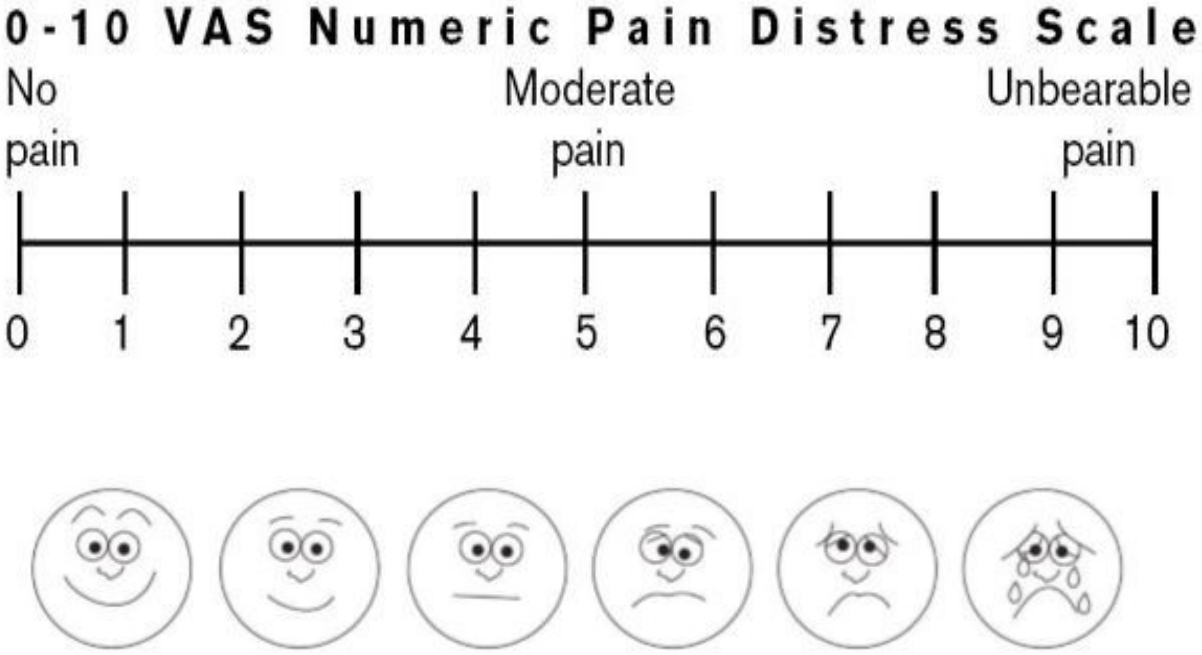
The average operative time is 50 mins (ranging 20 – 80 mins)

In cases of uneventful recovery all patients were discharged after 24 hrs.

- The main outcome measure is mean postoperative pain score measuring using VISUAL ANALOG SCALE on 1^{st}, 7^{th} and 10^{th} post operative days.

All patients were given standard dose 50mg i.m of Diclofenac sodium postoperative analgesia in bolus form 8 hourly. All Patients were followed up at the day of discharge (24 hrs after operation) and as an outpatient at 1^{st} week (7^{th} day) and 10^{th} day after the operation.

Information collected from the proforma was entered into SPSS version 16.0 for analysis. Quantitative variables like age and pain was presented in the form of mean $\pm$ S.D. T-test was used to compare the mean pain score in both groups. P value$\leq$ 0.05 was considered as significant.



0-1 : No/negligible pain

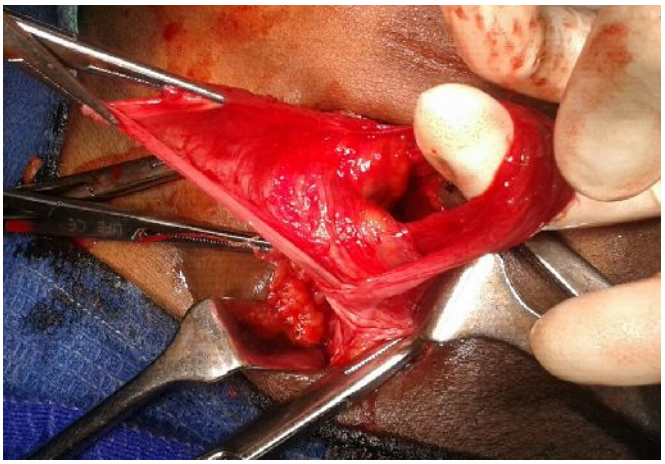
2-4 : Mild pain

5-6 : Moderate pain

7-8 : Severe pain

9-10 : Unbearable pain

At incision



Division of Sac

(a)

(b)

Fig. 12 Sac Ligation (a) and Sac Non-Ligation (b)

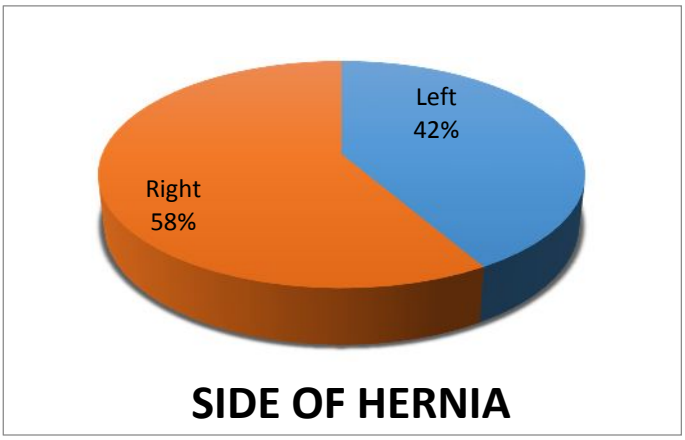
OUTCOME:

The collected data was analysed with SPSS 16.0 version.To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in Independent groups (With & Without SAC) Mann-Whitney U test was used. For the repeated measures (Day 1,7 & 10) the Friedman test was used.To find the significance in categorical data Chi-Square test was used. In all the above statistical tools the probability value .05 is considered as significant level.

RESULTS

a) Side Of Hernia:

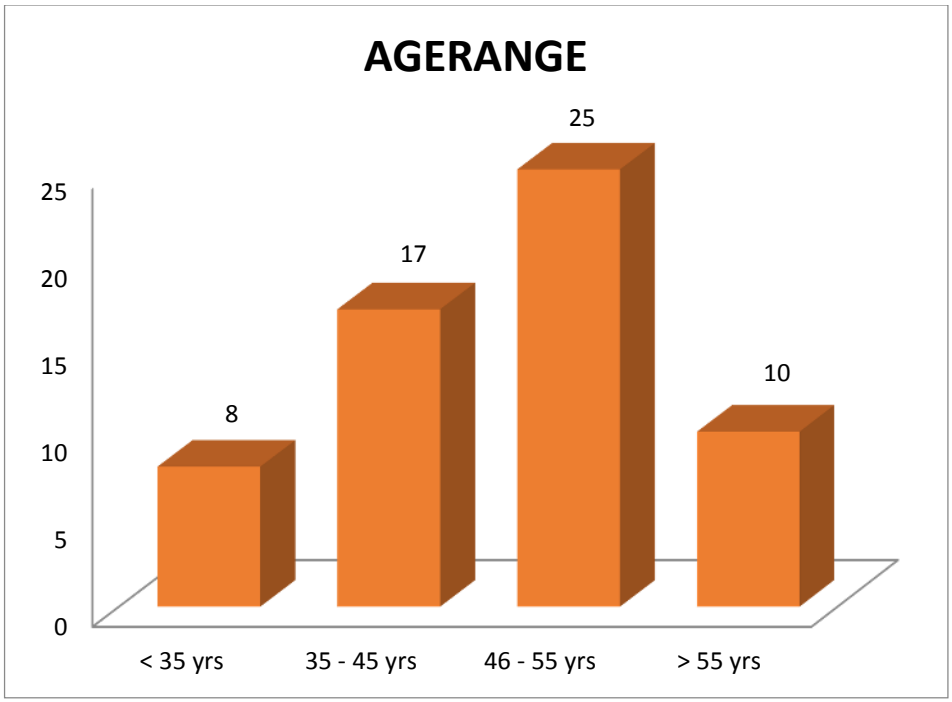
- 25 patients had Left inguinal hernia (42%) as compared to 35 of them who had Right Inguinal Hernia (58%).



Graph. 1 – Side of Hernia

b) Age Wise Distribution:

- 41% of individuals were in the age group of 46-55 yrs.
- 13% of individuals were in the age group of <35yrs.



Graph.2 Age Range

AGERANGE					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 35 yrs	8	13.3	13.3	13.3
	35 - 45 yrs	17	28.3	28.3	41.7
	46 - 55 yrs	25	41.7	41.7	83.3
	> 55 yrs	10	16.7	16.7	100.0
	Total	60	100.0	100.0	

Tab.1 Age Range

Crosstab					
			Groups		Total
			WITH SAC	WITHOUT SAC	
AGERANGE	< 35 yrs	Count	4	4	8
		% within Groups	13.3%	13.3%	13.3%
	35 - 45 yrs	Count	8	9	17
		% within Groups	26.7%	30.0%	28.3%
	46 - 55 yrs	Count	12	13	25
		% within Groups	40.0%	43.3%	41.7%
	> 55 yrs	Count	6	4	10
		% within Groups	20.0%	13.3%	16.7%
Total		Count	30	30	60
		% within Groups	100.0%	100.0%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	.499[a]	3	.919
Likelihood Ratio	.502	3	.919
Linear-by-Linear Association	.176	1	.675
N of Valid Cases	60		

- There is no Age bias in the selection of patients between the two groups as denoted by a p value of 0.919

c) Complications:

- Both the groups A and B had similar incidence of complications (seroma), 13.3%(4 patients).

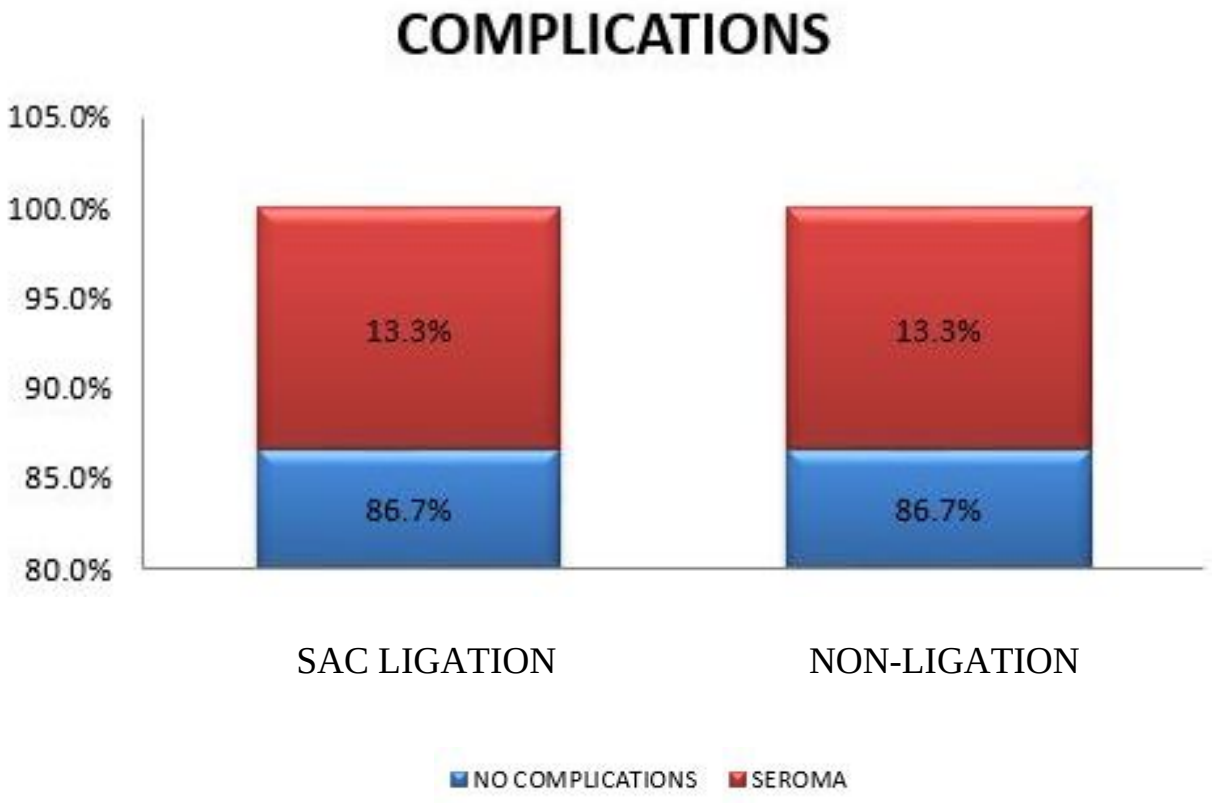


Fig. 3 Complications

d) Postoperative PAIN:

I. POD-1:

- 13 Patients (43.3%) experienced mild pain, and 17 patients (56.7%) experienced moderate pain in Group A (Sac ligation).

- 28 Patients (93.3%) experienced mild pain, and 2 Patients (6.67%) experienced moderate pain in Group B (Sac non-ligation).

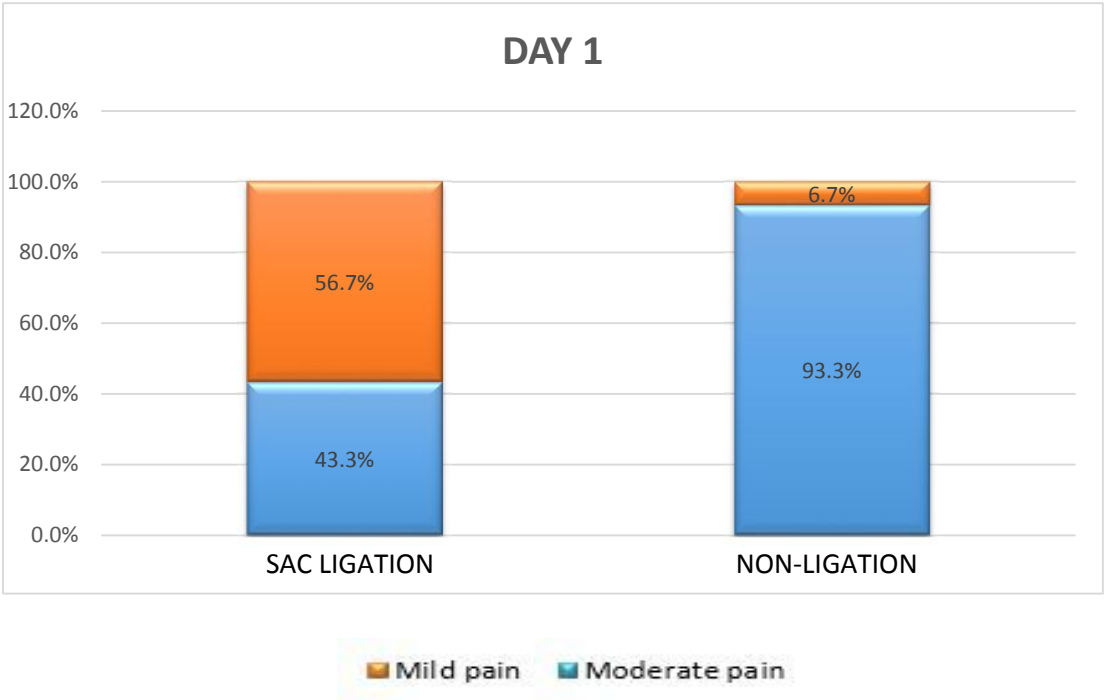


Fig. 4(a) Postoperative Pain POD-1

Chi-Square Tests					
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	17.330[a]	1	**.005**		
Continuity Correction[b]	15.096	1	.005		
Likelihood Ratio	19.170	1	.006		
Fisher's Exact Test				.005	.005
Linear-by-Linear Association	17.041	1	.005		
N of Valid Cases	60				

Chi Square tests show that there is a significant difference in the postoperative pain between the two groups (p=0.005)

II. POD-7:

All 30 patients (100%) experienced mild pain in Group A (sac ligation), whereas 6 patients (20%) experienced no/negligible pain in Group B (non-ligation).

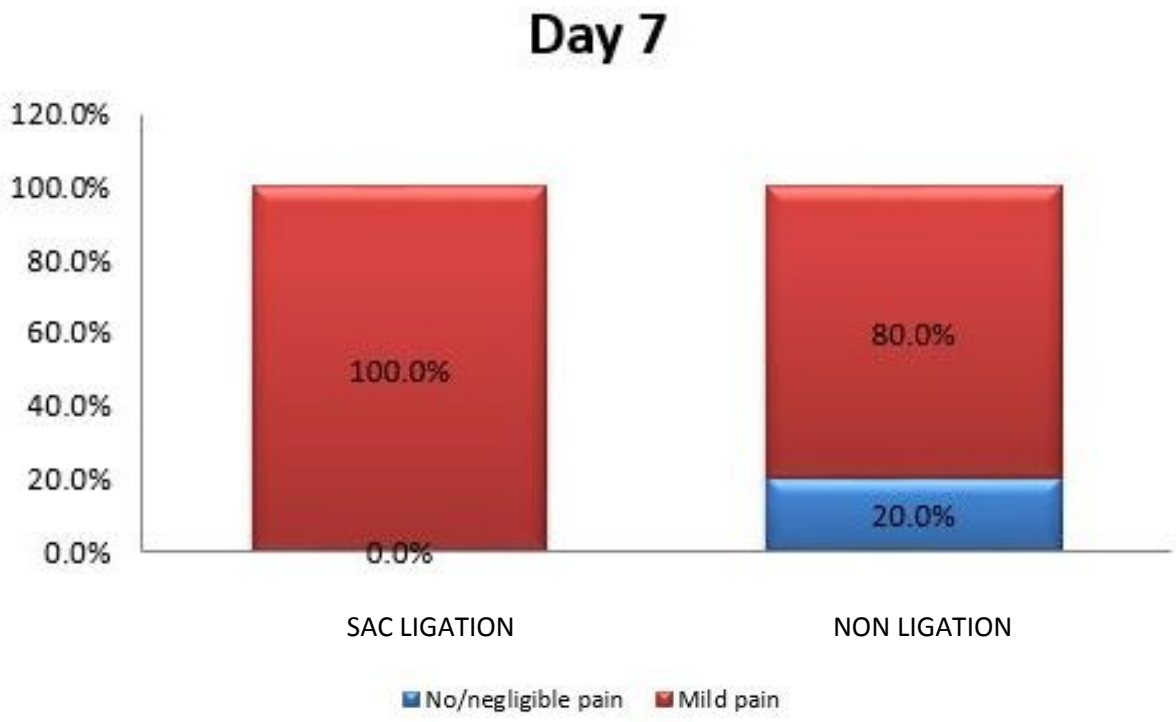


Fig.4(b) Postoperative Pain POD-7

Chi Square tests demonstrate a significance value of p=0.010, which shows a difference in pain on POD-7 in both the Groups.

Chi-Square Tests					
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	6.667[a]	1	**.010**		
Continuity Correction[b]	4.630	1	.031		
Likelihood Ratio	8.986	1	.003		
Fisher's Exact Test				.024	.012
Linear-by-Linear Association	6.556	1	.010		
N of Valid Cases	60				

III. POD-10:

- 26 (86.7%) Patients in Group A (sac ligation) experienced mild pain while 4 of them (13.3%) had no or negligible pain.
- 6 patients (80.0%) in Group B (non ligation) experienced mild pain while 24 of them (20.0%) had no or negligible pain.

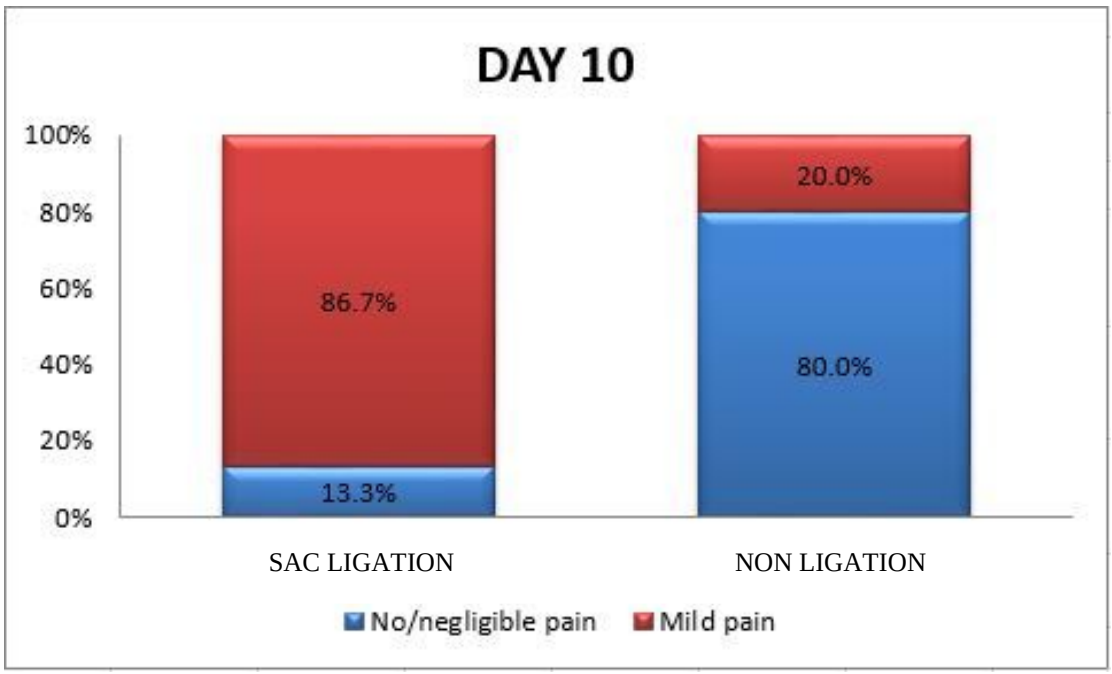
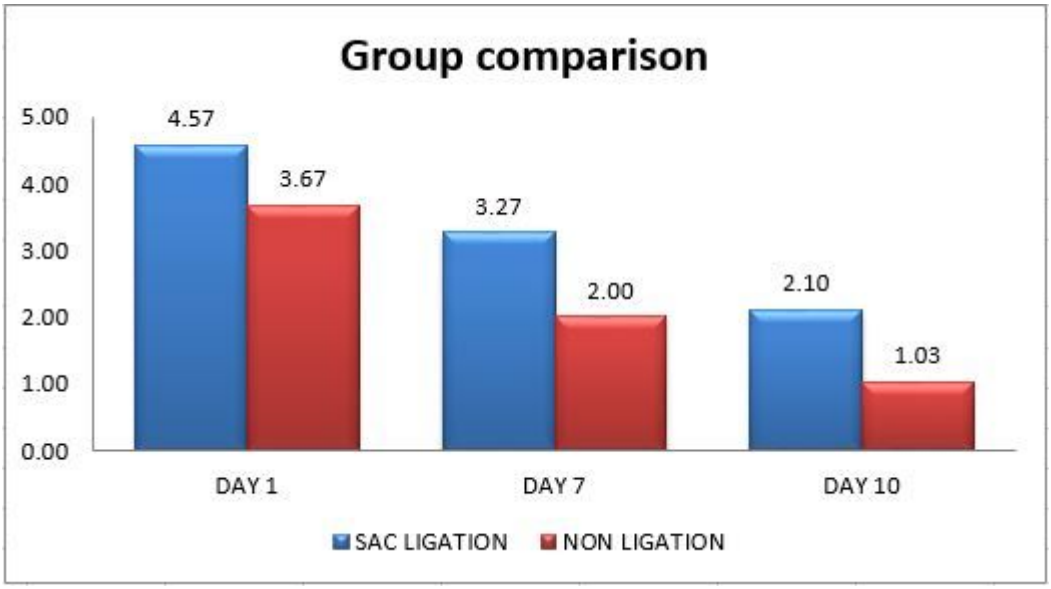


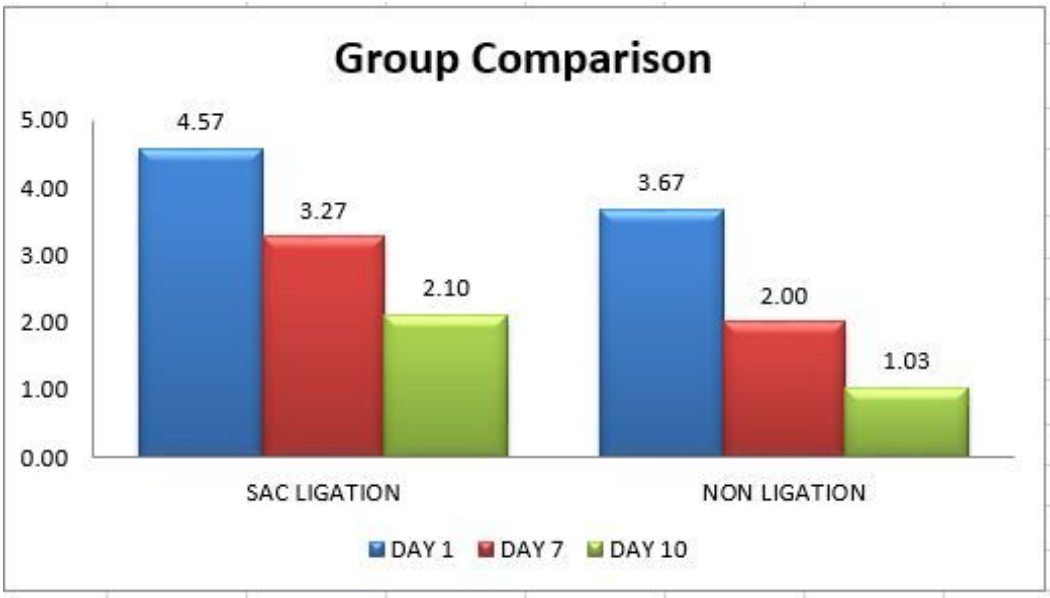
Fig. 4(c) Postoperative Pain POD-10

Crosstab					
			Groups		Total
			WITH LIGATION	WITHOUT LIGATION	
DAY10RANGE	No/negligible pain	Count	4	24	28
		% within Groups	13.3%	80.0%	46.7%
	Mild pain	Count	26	6	32
		% within Groups	86.7%	20%	53.3%
Total		Count	30	30	60
		% within Groups	100.0%	100.0%	100.0%

Chi-Square Tests					
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	26.786[a]	1	**.005**		
Continuity Correction[b]	24.174	1	.010		
Likelihood Ratio	29.326	1	.008		
Fisher's Exact Test				.005	.005
Linear-by-Linear Association	26.339	1	.005		
N of Valid Cases	60				

Chi Square tests demonstrate a significant difference in postoperative pain among both the Groups with p=0.005





Comparison between Group A & B, Postoperative Day VAS Scores

- Significance value after comparison of pain VAS scores in people who underwent Sac ligation (Group A) and Non ligation (Group B) is plotted below.

POD	Mean VAS score (A-Sac Ligation)	Mean VAS score (B-Non ligation)	SIGNIFICANCE
1	4.57 ± 0.5	3.67 ± 0.61	0.005
7	3.27 ± 0.74	2.00 ± 0.64	0.01
10	2.10 ± 0.61	1.03 ± 0.62	0.005

Tab. 3 Comparison of Mean VAS Score

e) <u>Recurrence :</u>

No recurrence occurred in both the Groups.

DISCUSSION

This study shows that non ligation of sac and leaving the sac open in inguinal hernia repair does not alter the recurrence rate. Recent studies have shown that, during abdominal surgery, within 2-3 days the peritoneum heals rapidly, leaving no adhesions, regardless of the size of the defect[34] and leaving the peritoneum open is not associated with wound failure[35].

Despite this traditional teaching on open hernioplasty emphasizing on suture ligation of the peritoneal end of sac following its transection at the level of deep ring, recent reports have stated that, leaving the sac unligated following transection does not alter the outcome. This study is backed by several studies on peritoneal healing which states that metamorphosis of in situ mesodermal cells in the raw areas promote peritoneal healing resulting in rapid healing of even large defects.

The place of non-ligation[42-44], was well documented by Smedberg et al[33], who presented the only prospective and controlled study of either ligation and excision of the sac or excising the sac as deep as possible, then leaving it open without ligation or transfixation. Their follow-up was rather short (2-3 years). The

study showed that leaving the sac open does not compromise the repair and results in less post-operative pain.

Non-ligation does not have any early or late effects on repair integrity. "To ligate or not to ligate" is important since non-ligation may be advantageous without increasing the morbidity. It limits the dissection, reduces the risk of injury to the spermatic cord and prevents further morbidity[45,46] and thereby makes the repair more complete and rapid[33]. Ligation, on the other hand, needs more dissection and causes greater post-operative discomfort[33]. It has also no added advantage in improving wound failure rate.

LIMITATIONS OF THE STUDY:

1) Sample size is less to confront on the results of non-ligation of sac
2) Duration of follow up (6 months), is rather short to comment on the long term sequelae.
3) The study is done only for irreduceable, non sliding hernia and hence could not be used for all Inguinal hernia cases.

CONCLUSION

High Ligation of the hernia sac in Lichtenstein's inguinal hernia surgery is not only deemed unnecessary and time consuming but also causes increased postoperative pain. Recurrence rates are similar in people who undergo Sac ligation and Sac non ligation.

SUMMARY

Sac excision and Invagination without ligation does not have any adverse effect on repair integrity. They limit the dissection and reduce the risk of injury to the spermatic cord and surrounding structures, thereby preventing further morbidity.

In the present study " EFFECT OF HIGH SAC LIGATION ON POSTOPERATIVE PAIN DURING LICHTENSTEIN'S INDIRECT INGUINAL HERNIA REPAIR ",58% (35) of patients came with Right Inguinal hernia. 41% of the individuals were clustered in the age group of 46-55 yrs, whereas 35% were <35 yrs of age group.

The age related distribution among the two groups showed p=0.919, which states that there was no bias in the selection of patients between two groups.

Both the groups had a complication (seroma) rate of 13.3% (4 patients), denoting that seroma was not a confounding factor in producing postoperative pain.

Based on the VAS score the postoperative pain between Group A and B were compared on POD-1, 7 & 10. The mean postoperative pain on **POD-1** in Group A was 4.57 ± 0.5, Group B – 3.67 ± 0.61 . On **POD-7** the mean VAS score in Group A was 3.27 ± 0.74, in Group B – 2.00 ± 0.64. On **POD-10** the mean VAS score was, Group A – 2.10 ± 0.61, Group B – 1.03 ± 0.62. The p value between the two Groups on **POD-1** was **p=0.005**, in **POD-7** it is **p=0.010**, in **POD-10** it is **p=0.005**.

There were no recurrences recorded among the two Groups in the follow up period of 6 months.

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PROFORMA

- NAME : SL. NO:
- AGE /SEX:
- ADDRESS WITH CONTACT NUMBER:
- IP NO:
- DATE OF ADMISSION:
- DATE OF SURGERY:

HISTORY OF PRESENTING ILLNESS:

PAST HISTORY:

- WHETHER A KNOWN CASE OF DM/HYPERTENSION/ASTHMA/TB/EPILEPSY/CARDIAC ILLNESS
- H/O SIMILAR EPISODES IN THE PAST, IF ANY:

CLINICAL EXAMINATION:

GENERAL EXAMINATION: TEMP: P.R: B.P: R.R

SYSTEMIC EXAMINATION:

CVS

RS

PER ABDOMEN:

LOCAL EXAMINATION of INGUINOSCROTAL REGION

CLINICAL DIAGNOSIS:

Investigations:

HEMATOLOGY	
HB	
PCV	
RBC	
TC	
DC	
PLT	
ESR	
RBS	
Blood UREA	
Serum CREATININE	
S.Na+	
S.K+	
S.Cl-	
S.HCO3-	

CHEST X RAY :

ABDOMEN X RAY:

USG ABDOMEN:

PATIENT CLINICAL COURSE:

OUTCOME OF TREATMENT:

INFORMED CONSENT

Name: Age/ Sex: IP:

I herewith declare that I have been explained in a language fully understood by me regarding the purpose of this study, methodology, proposed intervention, plausible side effects, if any and sequelae.

I have been given an opportunity to discuss my doubts and I have received the appropriate explanation. I understand that my participation in this study is completely voluntary and that I am free to withdraw from this study at anytime without any prior notice &/ or without having my medical or legal rights affected.

I permit the author and the research team full access to all my records at any point, even if I have withdrawn from the study. However my identity will not be revealed to any third party or publication.

I herewith permit the author and the research team to use the results and conclusions arising from this study for any academic purpose, including but not limited to dissertation/ thesis or publication or presentation in any level. Therefore, in my full conscience, I give consent to be included in the study and to undergo any investigation or any intervention therein.

Patient's Sign Investigator's Sign

(Dr.N.NIYAS AHAMED)

Patient Information Module

You are being invited to be a subject in this study.

Before you participate in this study, I am giving you the following details about this trial, which includes the aims, methodology, intervention, possible side effects, if any and outcomes:

All patients diagnosed with inguinal hernia on clinical grounds will be included in this study. A detailed clinical history will be taken following a standardized proforma. A detailed clinical examination will be made and relevant basic investigations will be done at the time of admission. Effect of High Sac Ligation in Lichenstein's Indirect Inguinal Hernia Repair on Postoperative pain will be evaluated. The results arising from this study will be analyzed and used for academic purposes. You will be given clear instructions at every step and you are free to ask/ clarify any doubts. Your identity will remain confidential. You are free to withdraw from this trial at any point of time, without any prior notice &/ or without any medical or legal implications.

I request you to volunteer for this study.

Thanking You,

Investigator's Sign Patient's Sign

(Dr.N.NIYAS AHAMED) (Name:)

KEY TO MASTER CHART

Side of Hernia:

R- Right
L- Left

Age: M- Male

IP No. – In Patient Number

Comorbidities: 1-Smoking, 2- Alcoholic, 3- Hypertensive

Complications: 1- No complications, 2- Seroma, 3- Recurrence

GROUP A : LICHTENSTEIN REPAIR WITH SAC LIGATION

GROUP A : HERNIA REPAIR WITH SAC LIGATION									
S.NO.	NAME	AGE	IP NO	SIDE OF HERNIA	Comorbidities	VAS PAIN SCORE			Complications
						DAY 1	DAY 7	DAY 10	
1	SUNDAR	47/M	1514075	R	1,2	4	4	1	1
2	BALARAMAN	55/M	1514084	R	2,3	5	3	3	1
3	AZHAGIRI	29/M	1516910	R	None	5	4	2	1
4	GAJENDRAN	47/M	1516917	R	1	5	2	2	1
5	JAMES	60/M	1519077	L	1,2,3	5	3	2	1
6	PRABHAKARAN	34/M	1519748	R	2	5	3	3	2
7	ABDUL KANI	39/M	1521051	R	None	4	3	2	1
8	SELVAMANI	35/M	1523182	L	2	4	4	2	1
9	GUNASEKAR	55/M	1523918	L	1,2	5	4	1	2
10	ASHOK	60/M	1523814	L	1,2,3	4	2	3	1
11	ARUL	40/M	1525115	L	1	5	4	1	1
12	MUNUSAMY	50/M	1525133	L	1,2,3	4	4	2	1
13	RAJA	45/M	1525121	R	2	5	4	2	1
14	RAVINDRAN	42/M	1526650	R	None	5	3	3	1
15	RAVI	39/M	1529732	R	1	5	3	2	1
16	KUMARESAN	57/M	1529690	R	1,2,3	4	3	2	1
17	SEKAR	43/M	1529682	L	1	4	2	2	1
18	KARTHICK	21/M	1532174	R	None	5	4	2	1
19	ABIBULLAH	46/M	1529717	L	3	4	4	3	1
20	KODHANDAM	55/M	1535068	R	1	5	3	2	2
21	BAKKIR AHMED	55/M	1534718	R	None	5	4	3	1
22	KRISHNAN	60/M	1541820	L	3	4	4	1	1
23	SUDHAKAR	46/M	1541899	L	1,2	5	3	2	1
24	JAISHANKAR	41/M	1542358	R	None	5	2	2	1
25	KUMAR	25/M	1543313	R	1	4	3	2	1
26	KASI	60/M	1544545	R	1,2,3	4	3	2	1
27	DHAMODARAN	58/M	1547395	R	1,2,3	4	4	2	1
28	KADHER	55/M	1547628	L	3	5	4	3	2
29	GANESAN	52/M	1541131	R	1,2	5	3	2	1
30	SIVANESAN	48/M	1551098	L	1	4	2	2	1

GROUP B: LICHTENSTEIN REPAIR WITHOUT SAC LIGATION

GROUP B : HERNIA REPAIR WITHOUT SAC LIGATION									
S.NO.	NAME	AGE	IP NO	SIDE OF HERNIA	Comorbidities	VAS PAIN SCORE			Complications
						DAY 1	DAY 7	DAY 10	
1	ASAN MEERAN	56/M	1514232	L	None	3	2	1	1
2	KALIAPPAN	30/M	1517431	R	1,2	4	3	1	1
3	MADURAI MUTHU	53/M	1517862	L	2	3	2	1	1
4	BALASUBRAMANI	55/M	1519364	L	2,3	4	2	1	2
5	VELAYUDHAM	42/M	1523861	R	1,2	5	3	2	1
6	ALLAH BASHA	55/M	1523998	L	3	3	1	1	1
7	SHAHUL HAMEED	51/M	1527643	R	None	3	1	0	1
8	PARASURAMAN	55/M	1527986	R	1,2	4	1	1	1
9	YESAMUTHU	43/M	1529875	R	None	3	1	0	1
10	SIGAMANI	60/M	1536421	R	1	4	2	2	1
11	GANESAN	48/M	1534486	L	1,2	4	2	1	2
12	ABBAS	55/M	1537143	L	None	3	2	1	1
13	MUNUSAMY	36/M	1538092	R	2	4	2	1	1
14	ZIAUDEEN	28/M	1538156	R	None	4	2	2	1
15	KRISHNAN	56/M	1540125	R	1,3	4	2	0	2
16	RAMARAJAN	42/M	1541127	R	2	3	3	0	1
17	MANI	55/M	1542789	R	1,2	3	1	1	1
18	DURAIRAJ	51/M	1543347	R	1	4	2	1	1
19	RAMASAMY	50/M	1547079	L	1	3	1	1	1
20	WAJITH	35/M	1549563	L	None	4	2	2	1
21	KAMARAJ	45/M	1553210	L	2	5	2	1	1
22	KARTHIKEYAN	29/M	1552548	R	None	4	2	1	1
23	RAMU	45/M	1552891	L	1	4	2	0	1
24	SEKAR	48/M	1554098	R	1,2,3	4	3	2	1
25	RAJASEKHAR	39/M	1528760	L	None	3	3	1	1
26	NATRAJAN	48/M	1524691	R	1,3	3	2	1	2
27	RAJANGAM	56/M	1539801	L	3	4	2	1	1
28	KUMAR	43/M	1540821	R	2	4	2	1	1
29	RAJESH	32/M	1544432	L	1,2	4	2	1	1
30	SHANMUGAM	51/M	1546098	R	1,2	3	3	2	1

INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Effect of High Sac ligation on postoperative pain during Lichtenstein's indirect inguinal Hernia repair.

Principal Investigator : Dr. N Niyas Ahamed

Designation : PG M S (General Surgery)

Department : Department of General Surgery
Government Stanley Medical College,
Chennai-01

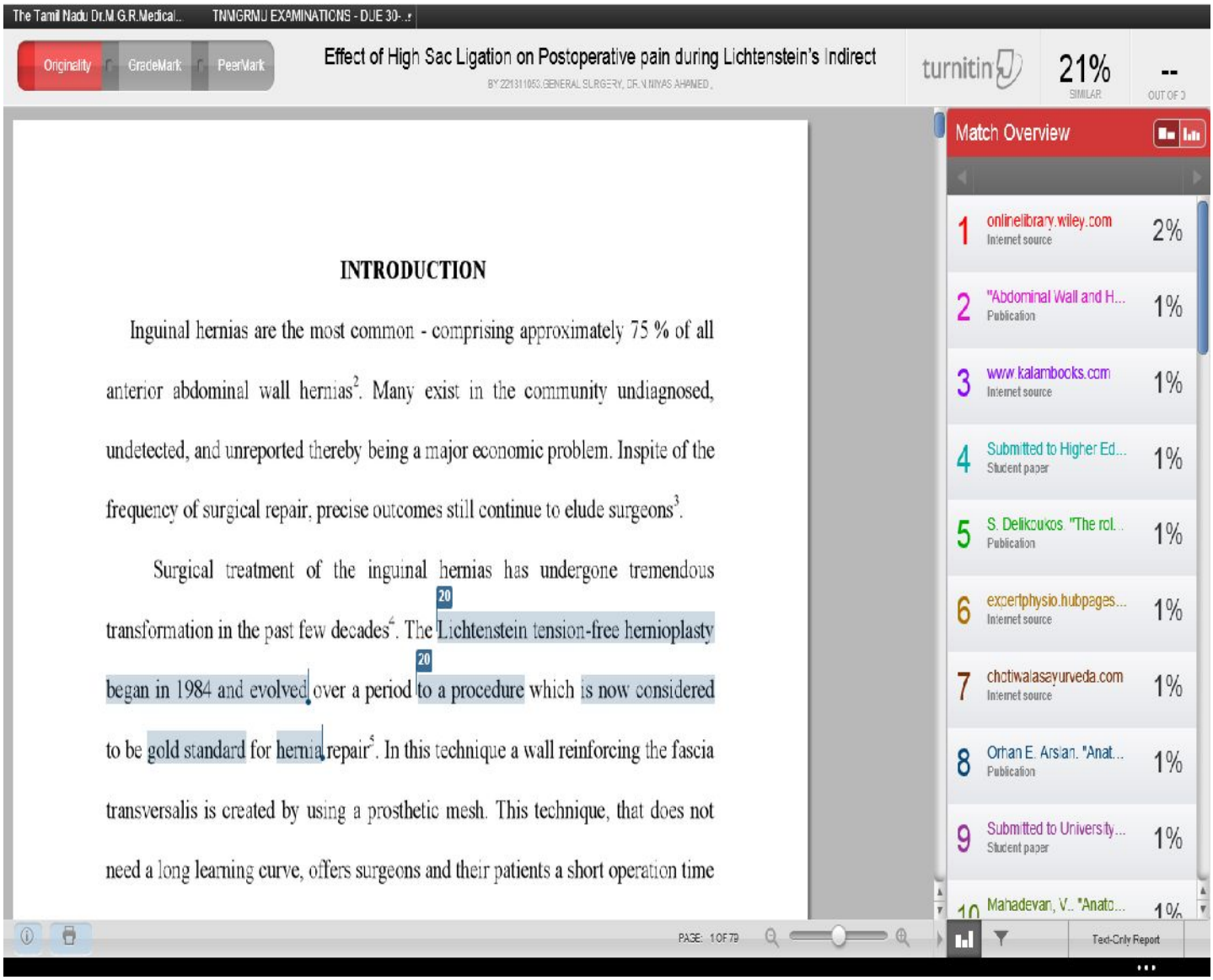
The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 26.11.2014 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

MEMBER SECRETARY,
IEC, SMC, CHENNAI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INTRODUCTION
Inguinal hernias are the most common - comprising approximately 75 % of all anterior abdominal wall hernias[2]. Many exist in the community undiagnosed, undetected, and unreported thereby being a major economic problem. Inspite of the frequency of surgical repair, precise outcomes still continue to elude surgeons[3].
Surgical treatment of the inguinal hernias has undergone tremendous transformation in the past few decades[4]. The Lichtenstein tension-free hernioplasty began in 1984 and evolved over a period to a procedure which is now considered to be gold standard for hernia repair[5]. In this technique a wall reinforcing the fascia transversalis is created by using a prosthetic mesh. This technique, that does not need a long learning curve, offers surgeons and their patients a short operation time
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